Division of Communicable Disease Control (DCDC)

Appendix A:
Web-CMR Requirements

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Introduction

Purpose of this document

The purpose of this document is two-fold:

- To provide a vehicle for presenting Web-CMR technical and business requirements.
- To provide supporting information about the procurement of a web-based electronic disease surveillance system for the California Department of Health Services (CDHS), Division for Communicable Disease Control (DCDC) and it's affiliated Local Health Departments (LHDs).

This document contains the following information:

- **Overview**: a comprehensive overview of the Web-CMR project.
- **Scope**: a brief high-level scope of the project.
- **Technical and Business requirements**: technical and business requirements for State and Local Health Departments (LHDs) for the surveillance and reporting of communicable disease.

Note: For information about the Web-CMR companion project **Electronic Laboratory Reporting (ELR)** please see the companion ELR RFP (07-65624).

Overview

This section provides a brief overview of the DCDC goals supporting the procurement of a Web-CMR system for the State of California.

About the CDHS, DCDC

The CDHS is committed to successfully administering a broad range of public health and health care coverage services to the population of California.

The purpose and mission of the DCDC division of the CDHS is "to provide surveillance, investigation, and control of more than 80 communicable diseases and conditions in California."

Working with State offices and sixty-one LHDs in California, the DCDC is actively involved in monitoring infectious diseases in the State through science-based disease prevention and control efforts.

For additional information about the CDHS, visit the website at: http://www.dhs.ca.gov/

DCDC primary goals for infectious disease control

The DCDC has identified the following primary goals required to support infectious disease control activities in the State:

- Improve laboratory capacity and develop more accurate and efficient diagnostic methods for new bacterial, parasitic, viral, and Rickettsial diseases.
- Expand and enhance infectious disease surveillance, detection, and tracking, including:
  - Automate and improve local and state reporting (through use of the Internet) of infectious diseases to assure timely and accurate assessment.
  - Work with agencies involved in food safety to implement a statewide microbiological monitoring program that will isolate, trace, and eliminate emerging pathogens in foods.
  - Develop electronic laboratory reporting to speed response time to disease outbreaks.
- Improve the capacity and readiness at both state and local public health levels to assure disease crisis intervention to control outbreaks and prevent the spread of infectious diseases. DCDC experts act as the epidemiological response team for emerging and re-emerging diseases at the regional level.
- Develop and improve systems, immunization registries and other links with private and public health care providers.
- Expand partnerships with health plans, other agencies such as the California Department of Food and Agriculture and Department of Corrections, and agriculture-related businesses. These partnerships will improve prevention activities, identify and adopt best practice guidelines, and institute quality control measures to minimize the potential for deadly infectious agents to spread among the population.

- Use population-based methods and channels to inform, educate and communicate disease prevention information to health care providers, policy makers, and communities at risk of infectious diseases.
- Thoughtfully and effectively address the disparity in health status and the burdens of infectious disease in California's ethnic, age and gender groups.

How a Web-CMR system supports DCDC goals

To accomplish the goals listed above, the DCDC seeks to procure an electronic disease surveillance system. The California Electronic Disease Surveillance System (CA-EDSS, code named "Web-CMR") will be used by the State DCDC as well as by LHDs in the State of California. This statewide, Web-CMR system should encompass, but is not limited to the following purposes:

- **Electronic reporting**: Electronic reporting of communicable disease and environmental exposure information from doctors/clinics/nurses/laboratories to state and local health departments and to the CDC. As a primary goal, the Web-CMR system will provide an electronic web-based Confidential Morbidity Report (CMR) form for providers, clinics, and nurses to report cases of communicable diseases. All entered data would reside in a shared database accessible to both local and state health departments for follow-up activities and surveillance. Robust role and jurisdiction-based security functions would ensure that system users would have access only to the correct data in the shared database.
- **Data access**: Once a notifiable condition is entered into the Web-CMR system, the data about this case should be accessible by local and state health departments. The data should also be available for reports, statistics and in-depth analysis as well as provide a base for an early warning system. Ideally, all reporters (providers, other clinicians, LHDs, and laboratories submitting cases) should be able to see their own reports and compare them to the surrounding region and to the State, without compromising the security of individual patient data and reports. Further a primary goal for the System will be to meet CDC requirements for reporting confirmed cases of notifiable communicable disease and be compliant with relevant federal certification requirements for the Public Health Information Network (PHIN) PHIN-NEDSS.
- **Patient and case management**: Patient and case management for cases of communicable diseases and environmental investigations for the state health department and for local health departments.
- **Disease surveillance**: Surveillance of outbreaks of communicable diseases and environmental hazards.
- **Trend evaluation**: Evaluation of trends by performing searches and analyses of the data.

Multiple systems, both electronic and paper-based, are now used within the State of California to report, manage and control communicable diseases, and to allow automatic messaging of laboratory result data.

Local health departments receive reports of cases of communicable disease via paper forms, faxes or telephone calls. Follow-up activities to gather additional information are collected in local data systems or on paper and then sent via paper, fax, modem, and phone to the State. The State then processes and transmits required data to the Centers for Disease Control and Prevention (CDC).

Scope of Web-CMR Project

This section describes the proposed scope of the Web-CMR Project.

Structure of the DCDC – Branches, Programs, and Local Health Departments

The Division of Communicable Disease Control (DCDC) works in partnership with local, national and international health officials, health care providers, and the public to monitor health, identify and investigate existing and potential health problems, develop and implement prevention strategies, conduct research, provide education and training, and formulate and advise on public health policy.

DCDC is comprised of the following branches and programs. See the DCDC website for detailed information about each branch.

DCDC Branches and Programs

- Immunization Branch (IZB)
- Infant Botulism Treatment and Prevention Program (IBTPP)
- Infectious Disease Branch (IDB)
- Microbial Diseases Laboratory Branch (MDL)
- Office of Informatics and Surveillance (OIS)
- Sexually Transmitted Diseases Control Branch (STDCB)
- Tuberculosis Control Branch (TBCB)
- Viral and Rickettsial Disease Laboratory Branch (VRDL)

California Local Health Departments

There are 61 Local Health Departments in counties throughout California. For a list of California Local Health Departments with links to detailed information, see http://www.dhs.ca.gov/ps/dcdc/izgroup/shared/depts.htm (if clicking this link does not open your Internet browser, copy and then paste the link into your browser's address box).

Scope of Web-CMR Surveillance Reporting

The Web-CMR surveillance reporting scope includes but is not limited to the following capabilities. (Refer to RFP XXXX for detailed requirements.)

- Electronic Data Capture.
- Case Report and Contact Surveillance Reporting.
- Case and Contact Management.
- Outbreak Management.
- Integration of Electronic Laboratory Reporting for laboratory results.
- Analytic capability at the state and local level.

State-wide Scope

To meet the purpose and mission of each branch, DCDC needs to provide a State-wide service to LHDs, Providers, and Laboratories that will allow the state to monitor, investigate and control the 80 communicable diseases and conditions in California. (Disease reporting is mandated by the California Code of Regulations, Title 17, Sections 2500, *et. seq.*)

The core function of the DCDC is to conduct surveillance of active disease cases and their contacts. DCDC relies on timely and accurate provider and laboratory data for the identification of these cases, as well as for the detection and management of outbreaks. The analytic and evaluative use of data informs DCDC both in its setting of priorities and allocation of resources and in its response to state and local communicable disease programs, laboratories, and private providers.

- **Comprehensive centralized statewide surveillance and reporting system**: Implement a centralized statewide system to capture the various DCDC and LHDs' surveillance and laboratory data for cases, their contacts, and for patients that move between local jurisdictions. This reporting includes the California Confidential Morbidity Report (CMR), lab reports, surveillance forms, disease specific case management forms, field records, and the mandated CDC reports.
- **Statewide database with the ability to analyze surveillance data**: Integrate and interface with internal and external surveillance systems to permit an improved, comprehensive and more accurate collection of data for epidemiological analysis of the various diseases, providing better disease control and oversight of case management.
- **Ability to receive and transmit data from and to external surveillance systems, including the CDC**: Making existing, separate databases into a web-based technology will allow for enhanced data sharing between state and local partners, centralized maintenance of reporting systems, and provide California with a vehicle to report required data to the Centers for Disease Control. The system will provide the ability to comply with current and future reporting requirements from the CDC.
- **Ability to initiate and manage alerts**: The ability to identify and communicate triggering events will strengthen DCDC's ability to manage and respond to outbreaks, and respond to inter-jurisdictional issues.

- **A comprehensive, integrated case/outbreak management system:** A cross-jurisdictional case/outbreak management system to coordinate the identification and follow-up of cases and to coordinate interventions to prevent or control further spread of disease.

Local Health Departments, Providers, and Laboratories Scope

The local programs will capture data, respond to and manage outbreaks, and submit surveillance reports to the State DCDC. Local programs respond to reports of suspected diseases by both providers and laboratories and are responsible for the rapid identification and timely, appropriate treatment of cases, contacts, and high risk persons. Local programs provide oversight of case and contact management by private providers in their jurisdictions. The integrated Web-CMR must provide:

- **Capture of all CMR and electronic laboratory data via an electronic interface**: Capture and link CMR and electronic laboratory results through an integrated web-based surveillance system to improve the timeliness of notification of suspected disease, eliminate redundant data entry, and permit more rapid response by the local programs.
- **Centralized reporting of all CMR forms for LHDs**: Centralize the respective surveillance reporting to the DCDC to simplify and improve timeliness of reporting for local programs. In addition, inclusion of online instructions, forms, and Help tools will improve the accuracy and quality of reported data.
- **Ability to receive data from and transmit to external surveillance systems**: For LHDs with their own patient management or information systems, the ability to electronically submit and exchange data will reduce errors and eliminate redundant data entry. The ability to submit batch reports will particularly streamline data management for high morbidity conditions, especially for larger LHDs.
- **Case management**: Manage case and contact information to facilitate the monitoring of patients and enable effective surveillance reporting. Facilitate the exporting of datasets for local evaluation and monitoring and for the mandated surveillance reports.
- **Alerting and management of inter-jurisdictional issues**: Sending and receiving notifications, as well as the ability to transfer and share data on cases and contacts will improve the timeliness of follow-up for patients who move within California.
- **Outbreak management**: Group related cases of illness to conduct effective outbreak control measures for outbreak management.
- **Improved inter-jurisdictional response**: Local programs will be able to quickly inform other LHD of relevant lab results for patients moving out of their jurisdictions or when lab results are misdirected.

Requirements

1 Technical Requirements

1.1 Infrastructure

The electronic disease surveillance system will be implemented as a web-based solution, accessible by users throughout California. It is expected that the vendor selected will move towards full certification of the system in these particular areas as the CDC guidance evolves.

1.1.1 Infrastructure Requirements			
Rank	**Demo**	**Req ID**	**Description**
D	**Y**	**1.1.1.1**	The System must be web-based with minimal client installations required. If any part of the System is not web-based or requires additional client installations describe these in detail and what types of installations they require.
D	**Y**	**1.1.1.2**	The System must provide the ability to enforce the use of PHIN and CalPHIN concepts, value sets, and code systems for specified variables.
D	**Y**	**1.1.1.3**	The System must use PHIN vocabulary standards for data interchange according to PHIN messaging specifications.
D	**Y**	**1.1.1.4**	The System must be compatible with all Windows Internet Explorer versions 6.0 and other commonly used browsers. List all browsers and versions that are supported. Describe any changes beyond the default installation of the browser that are necessary.
D	**Y**	**1.1.1.5**	The Application server/web server layers must run on the current ITSD standards (currently, Microsoft Windows 2003) Server. Vendors must indicate all supported application/web servers and version numbers in bid response.
D	**Y**	**1.1.1.6**	The Application must utilize N-tier design: presentation, application, and data layers. Each layer is physically separated by firewall segments.
D	**N**	**1.1.1.7**	The System must use standard firewall ports to communicate between the zones.
D	**Y**	**1.1.1.8**	The entire Application must utilize Microsoft .Net technologies.

1.1.1 Infrastructure Requirements			
Rank	**Demo**	**Req ID**	**Description**
M	**N**	**1.1.1.9**	The solution infrastructure must provide a minimum of five (5) environments: Development; Production-Like Training; Production-Like User Acceptance; Production-Like Staging; and Production. The vendor must provide a technical diagram and description of the proposed infrastructure solution, as described above. The technical diagram must depict the architecture and design of the proposed solution. The description must also include a description of System hardware requirements. The technical diagram and description **must** be included in the response to this proposal.

1.2 Database

The electronic disease surveillance system database will reside on a server at a central location, accessible from the remote facilities via browser-based access. It is anticipated that the database will be deployed on an existing California database server. A separate reporting database from the main OLTP database may also be utilized.

Note: See "Database, Transactional" and "Database, Analytic" entries in the Glossary of Terms in this document.

1.2.1 Database Requirements			
Rank	**Demo**	**Req ID**	**Description**
D	**Y**	**1.2.1.1**	The System must use Microsoft SQL Server 2000 or 2005 as its database engine to adhere to the CDHS-ITSD-DTS platform standards.
D	**N**	**1.2.1.2**	The System must retain transactional data for a minimum of 5 years after case is closed as required by program needs (PMT to identify specific disease(s)). Must have online access to data (legacy + current). System performance for the transactional database must adhere to limitations specified under Application Infrastructure Requirements.
D	**N**	**1.2.1.3**	The System must indefinitely retain all data for use by programs.
D	**Y**	**1.2.1.4**	The System must provide the ability to accept, store, and reproduce all the PHIN messages as specified in the PHIN key performance measures without losing semantic integrity. (http://www.cdc.gov/phin)
D	**Y**	**1.2.1.5**	The System variables must be stored in tables accessible and maintainable by a CDHS system administrator via the application.

1.2.2 PHIN Requirements			
Rank	**Demo**	**Req ID**	**Description**
O	**N**	**1.2.2.1**	It is desirable that the system support the relevant PHIN EED, CFC, and CLS functional requirements as California intends to meet as many of these requirements as possible through the acquisition of Web-CMR and expects the vendor selected to move towards full certification of its system in these particular areas as the CDC guidance evolves.
M	**N**	**1.2.2.2**	The System must be compliant with the PHIN logical data model.
M	**Y**	**1.2.2.3**	For all data elements captured by the system (including all morbidity and laboratory results data) the application must have the capability to interoperate this data using established vocabulary (e.g. LOINC and SNOMED) and common data element standards established by the CDC's Public Health Information Network (e.g. PHIN VADS, CDC Common Data Elements Implementation Guide, PHIN Functional Requirements, Notifiable Disease Mapping Tables and others). (See www.cdc.gov/phin).

1.2.3 Data Dictionary Requirements			
Rank	**Demo**	**Req ID**	**Description**
M	**Y**	**1.2.3.1**	The System must provide the ability for CDHS to generate, store, and manage data dictionaries that contain common data elements, such as Field Name, Description, Value, Value Label, Type, Length, Calculated, for all forms, messages, or exported data. The data dictionary should be able to be viewed both electronically and printed. The data dictionaries need to be linked variable by variable to the data exports for specific forms and/or reports. **Sample data dictionaries and related forms are provided in Appendix C.**

1.2.4 Log Requirements			
Rank	**Demo**	**Req ID**	**Description**
M	**Y**	**1.2.4.1**	The System must provide an audit trail for data entry, updates (recording new and changed values), and data reads/access. Logs must contain information including but not limited to user, IP address, date, time, and data elements entered, updated or read, and the values contained within the data elements.
M	**Y**	**1.2.4.2**	System audit functionality should be maintainable by the CDHS system administrator via the application.

1.2.4 Log Requirements			
Rank	**Demo**	**Req ID**	**Description**
M	**Y**	**1.2.4.3**	For users with the appropriate security permission, the System must provide the ability to view or print audit logs using role based security.
D	**N**	**1.2.4.4**	The System must provide exception reports and/or alerts based on events and/or patterns in system access logs as defined by business rules.
D	**N**	**1.2.4.5**	The System must provide logs that enable auditing of report, form, and case linking.

1.3 Security

The system must provide secure access, data integrity, and role-based data security. Access to data for all purposes must be controlled by roles. A role is associated with one or more permissions and jurisdictions which, taken together, control access to information. The role-based security must support non-uniform roles where people might have a mix of different roles and responsibilities.

1.3.1 Security Requirements			
Rank	**Demo**	**Req ID**	**Description**
M	**Y**	**1.3.1.1**	The System must use a unique User-ID (UID) and password (PSWD) sign-in for user authentication. **Provider Level**: Some administration of UIDs and PSWDs must be implemented. Also some provider authentication and approval must be implemented. **State and LHD Level (Admin & user)**: There will be an administrative body in charge of approving UIDs and PSWDs. This will be administered based on ITSD's approved procedure through Active Directory.
M	**Y**	**1.3.1.2**	The System must provide role-based security, providing appropriate user access to system functions which should be managed at the State and Local (LHD) level, as well as intermediate area and regional levels where applicable.
M	**Y**	**1.3.1.3**	The System must provide the ability to configure access to data distribution of alerts (user roles and privileges) by User, Role, Program, and Jurisdiction.
M	**Y**	**1.3.1.4**	For users with the appropriate security permission (CDHS system administrator), the System must provide the ability to add new, modify, and delete roles to the security model.

1.3.1 Security Requirements			
Rank	**Demo**	**Req ID**	**Description**
M	**N**	**1.3.1.5**	The System must utilize SSL v3 or TLS 1.0 or SFTP for all data transmissions.
M	**Y**	**1.3.1.6**	The System must utilize Microsoft Active Directory 2003 for user authentication and authorization.
M	**N**	**1.3.1.7**	The System must provide limits to maximum user idle time with minimal impact to session data based on business needs. A user with appropriate permissions should be able to configure time out parameters.
D	**Y**	**1.3.1.8**	The System must provide a time-stamped warning message to the user prior to a session timeout. The warning message will occur in sufficient time to offer the user an opportunity to continue the session without disruption. The warning message must display the approximate time remaining before the session timeout as appropriate. For example: "**Notice**: No activity has been detected for XX minutes. Your current Web-CMR session will timeout in approximately 10 minutes, please save your work.").
M	**Y**	**1.3.1.9**	System administration to be hierarchical to allow for delegation.
M	**N**	**1.3.1.10**	The System must follow HIPAA security standards http://www.hhs.gov/ocr/hipaa/ as it applies to Public Health.
M	**N**	**1.3.1.11**	The System must provide alternate options for stronger authentication than username and password such as digital certificates, web server authentication, etc. (i.e. 2FA).

1.3.1 Security Requirements			
Rank	**Demo**	**Req ID**	**Description**
D	**Y**	**1.3.1.12**	The Privacy Notice Agreement popup dialogs shown below should appear when the following actions occur: **At Log in**: When the user logs into the system, the following text should appear on a popup dialog: *Information contained on this site which would permit identification of any individual has been collected with a guarantee that it will be held in strict confidence, will be used only for surveillance purposes, and will not be disclosed or released without the consent of the individual in accordance with Section 308(d) of the Public Health Service Act (42 U.S.C. 242m).* *This information is restricted to the use of the intended user. Unauthorized or improper use of this information may result in administrative disciplinary action and/or civil and criminal penalties. By receipt of this information you indicate your awareness of and consent to these terms and conditions of use.* **When using data**: when the user attempts to generate, export, transmit, or print all data containing confidential patient names and/or other identifiers. Note that this data can only be exported or viewed by role permission at the LHD and State level. *Information contained on this form which would permit identification of any individual has been collected with a guarantee that it will be held in strict confidence, will be used only for surveillance purposes, and will not be disclosed or released without the consent of the individual in accordance with Section 308(d) of the Public Health Service Act (42 U.S.C. 242m).* *The information included in this report is restricted to the use of the intended recipient. Unauthorized or improper use of this information may result in administrative disciplinary action and/or civil and criminal penalties. By receipt of this information you indicate your awareness of and consent to these terms and conditions of use.*
M	**Y**	**1.3.1.13**	The following "confidential" statement should print on all documents printed directly from the web-based application. **Privacy Notice Text to appear on printed documents**: *Information contained on this form or report which would permit identification of any individual has been collected with a guarantee that it will be held in strict confidence, will be used only for surveillance purposes, and will not be disclosed or released without the consent of the individual in accordance with Section 308(d) of the Public Health Service Act (42 U.S.C. 242m).*

1.3.1 Security Requirements			
Rank	**Demo**	**Req ID**	**Description**
M	**Y**	**1.3.1.14**	The System must provide a secure hierarchical, disease-specific, permission structure to allow: • local staff to access only specified local data • "area" supervisors and staff to access cases from multiple LHDs • "regional" supervisors and staff to access cases from multiple areas • state supervisors and staff to access cases from multiple regions.
M	**Y**	**1.3.1.15**	The System must provide the ability for Regional DIS workers to simultaneously view all cases assigned to them, across jurisdictions (so they do not have to log on to each jurisdiction's Web-CMR portal to see their assignments for that jurisdiction).
M	**Y**	**1.3.1.16**	The System must provide the ability to add state investigators to local lists for assignment of investigations.
M	**Y**	**1.3.1.17**	The System must provide necessary data encryption as required by CDHS ITSD policy and prevailing standards such as PHIN or HIPAA.
M	**Y**	**1.3.1.18**	The System should provide the ability for users with appropriate authority and permissions to define jurisdictional areas and regions.

1.4 Application Infrastructure

1.4.1 Application Infrastructure Requirements			
Rank	**Demo**	**Req ID**	**Description**
M	**N**	**1.4.1.1**	The Source code must be placed in escrow to provide CDHS protection. This must be updated with each new release.
M	**N**	**1.4.1.2**	The System must initially provide the ability to support 2000 concurrent users.

1.4.1 Application Infrastructure Requirements			
Rank	**Demo**	**Req ID**	**Description**
M	**Y**	**1.4.1.3**	For users with the appropriate security permission, the System must provide the ability to add new organizations such as, labs, clinics, hospitals, etc., as required to a centralized "organization registry."
M	**N**	**1.4.1.4**	For 90 percent of the system transactions: • Require no more than 15 seconds to provide initial logon to the application. • Require no more than 3 seconds to provide responses to simple database queries, complete on-line updates to the database, and navigate from screen to screen.
M	**N**	**1.4.1.5**	The System must be available to users 24x7 except for regularly schedule maintenance or prescheduled updates.

1.4.1 Application Infrastructure Requirements			
Rank	**Demo**	**Req ID**	**Description**
M	**Y**	**1.4.1.6**	For users with the appropriate security permission, the System must provide the ability to create, configure, and maintain (add, modify, delete) forms, screens and validation rules, used for data collection. Examples include updating forms for a new disease or a new follow-up form/questionnaire, modifying and adding fields to existing forms (including demographics), as well as changing and adding views/lists in the System. **The specific capabilities required for form creation, modification, and maintenance are as follows:** • System will allow users with appropriate permissions to add fields to different sections of an existing form. • System will allow users with appropriate permissions to delete fields from different sections of an existing form. • System will allow users with appropriate permissions to retire fields from current forms. • System will allow users with appropriate permissions to edit fields within existing forms. • System will allow users with appropriate permissions to develop electronic forms that are printable and will look similar to the paper-based version of the form when printed. For example, users are familiar with the CDC-released paper-based version of the RVCT form (Report of Verified Case of Tuberculosis) and would desire a web-based form, when printed, to look very similar to the paper version of the form. • System will allow users with appropriate permissions to retire forms that are currently in the system. • System will allow users with appropriate permissions to delete forms that are currently in the system. • System will allow users with appropriate permissions to edit code sets associated with existing fields on a current form. • System will allow users with appropriate permissions to add validation rules associated with a current form. • System will allow users with appropriate permissions to edit validation rules associated with a current form. • System will allow users with appropriate permissions to retire validation rules associated with a current form. • System will allow users with appropriate permissions to delete validation rules associated with a current form.
M	**Y**	**1.4.1.7**	For users with the appropriate security permission, the System must provide the ability to develop and add supplemental forms as needed for data collection needs.
M	**Y**	**1.4.1.8**	For users with the appropriate security permission, the System must provide the ability to modify electronic implementation of the California CMR to be congruent with any/all alterations/updates to the paper version at any time.

1.4.1 Application Infrastructure Requirements			
Rank	**Demo**	**Req ID**	**Description**
M	**N**	**1.4.1.9**	The System data backup and recovery processes should have minimal impact on system availability.
M	**N**	**1.4.1.10**	The System upgrade procedures should have minimal impact on system availability.
M	**N**	**1.4.1.11**	The system shall be structured to make adherence possible to all CDHS Information Technology Services Division (ITSD) policies and procedures for data archival and recovery. *Note: It is CDHS ITSD policy to retain monthly data backups for one (1) year. The current month's data is backed up weekly.*
M	**N**	**1.4.1.12**	The System must provide the ability for "fail-over" functionality to alternate site.
O	**N**	**1.4.1.13**	The System must provide the ability to support mobile users. Describe supported devices, supported business functions, technical specifications, etc. If the system does not currently have this functionality, describe the future plans in this area, including potential timeline.
M	**N**	**1.4.1.14**	The System must provide the ability to support large number of users conducting activities under the burden of a high volume of laboratory and provider reports.
M	**Y**	**1.4.1.15**	The System must provide the ability for user-controlled vocabulary administration, including the ability to associate code-sets (value sets) with coded form variables for validation purposes, and to maintain the code-sets (e.g. dropdown choice lists and lists of valid codes per concept), i.e. supporting the addition and deletion of codes from code-sets without vendor programming assistance.
M	**Y**	**1.4.1.16**	The System must provide the ability to store a formal PHIN/CalPHIN value set identifier with each code set, and to retrieve coded value sets on the basis of this identifier as part of the vocabulary maintenance functionality.
M	**Y**	**1.4.1.17**	For users with the appropriate security permission, the System must provide the ability to configure all automated criteria defined.

1.5 Data Exchange / System Interface

The system will need to interface with CDC systems as well as some existing systems at CDHS.

1.5.1 Data Exchange / System Interface Requirements			
Rank	**Demo**	**Req ID**	**Description**
D	**Y**	**1.5.1.1**	The System must provide the ability to electronically transfer data (information) to CDC through NETSS until PHIN compliant mechanisms become available, at such time the system should support NEDSS reporting. http://www.cdc.gov/phin/kpm/KPM_RSv1.0.pdf
D	**N**	**1.5.1.2**	**Transmit TB Data to the State and to the CDC**: The System must provide the ability for the State TB Case Registry Administrator to transmit required TB Surveillance data to the Centers for Disease Control and Prevention (CDC). Transmittal of data would first be by upload to the current TIMS system, and in later development to the TB Program Area Module (TB PAM) when it becomes available.
D	**N**	**1.5.1.3**	For transmission of CDC mandated TB data (RVCT), the System must provide the ability to flag data transmission to ensure Web-CMR and CDC synchronization. Specifically, for CDC bound data, a transfer flag should be tripped when 1) a new record is entered, 2) an edit of an existing record happens, or 3) a deletion of an existing record happens. This flag could record N (=New), E (=edited), D (=deleted) or null, null meaning no information to be transferred. The System must provide the ability to additionally flag, when a record is transmitted for one of the three reasons mentioned above, to record receipt of an acknowledgment from the CDC system signifying that the CDC system indeed received the transfer.
D	**Y**	**1.5.1.4**	The System must provide the ability to send and receive messages to support investigation and outbreak management (OM) for identified suspect cases, providing the data needed to identify affected persons and their exposure levels, as well as to enable case management and exposure contact tracing (Early Event Detection PHIN Certification Functional Requirement 2.10.2.1) **Note**: If necessary can deploy system without this requirement, but vendor should work towards fulfilling this PHIN requirement.
O	**N**	**1.5.1.5**	External systems (users and/or applications) should be able to make data queries as well as data submission operations.
O	**N**	**1.5.1.6**	The System must provide the ability to interface with electronic health records systems such as Kaiser and other large providers. If this is not currently supported, please include plans for future development.

1.5.1 Data Exchange / System Interface Requirements			
Rank	**Demo**	**Req ID**	**Description**
D	**N**	**1.5.1.7**	For TB, the System must provide the ability to: • Receive electronic uploads of the *Class B Report on Alien with Tuberculosis CDC 75.17* and *Report of Sentinel Event forms*. • Receive electronic uploads of B-Notification data from CDC's Information on Migrating Populations (IMP) database • Interface with—or at minimum have a URL link—with the CDC's Electronic Disease Network (EDN) once operational.

1.6 Integration

The Web-CMR System infrastructure (database, application and web servers) will be deployed at a central site located at Sacramento, CA. In addition, many jurisdictions within California will continue to utilize their own separate local surveillance systems, rather than participating in direct use of the State-hosted Web-CMR system. In this section these jurisdictions are referred to as "non-participating jurisdictions" (NPJs). It is the intention that these separate systems of NPJs will eventually be integrated with the central State system in order to enable data transfer between all California jurisdictional systems (local and State). This integration will enable each jurisdiction (including the State) to have a complete view of surveillance activity. The planned integration includes data related to CMRs, lab reports, case investigations, and case report form data.

Note that in functional terms, these types of data transfers are also relevant between participating jurisdictions, but can be accomplished through system functions; i.e. without the requirement for messaging, since users from all participating jurisdictions would be logging in directly to the central system. This integration section only describes data exchange needs between totally disconnected systems.

Most of these integration requirements involve the exchange of HL7 messages. Some of the HL7 message implementation profiles (final message specifications) are still in development by CDC PHIN, with most predicted to be completed by early 2007 (per PHIN 2006 conference briefings.) In most cases, CalPHIN will be required to further specify and/or extend and adapt the CDC PHIN or HL7 specifications. Therefore these requirements refer generically to "current PHIN and CalPHIN specifications" or standards. The specifics of the standard HL7 versions and implementation guides will be provided in later documentation.

The following functions (further detailed within the Integration Requirements table below) are some of the primary integration needs to be considered:

- Initial provider reports (CMRs) or lab reports may need to be transferred to another jurisdiction for follow-up and reporting. This might include transfer to a separate system, or receipt from a separate system.
- Investigations underway may need to be transferred.

- Provisional or final case reports submitted by local NPJ's to the State need to be received, and if provisional, such reports should be updatable. Additionally, it would be desired that the system be able to message feedback to the separate system.
- In case of a cross-jurisdictional outbreak, case-sharing would be desired.

1.6.1 Integration Requirements			
Rank	**Demo**	**Req ID**	**Description**
D	**Y**	**1.6.1.1**	**CMR and Lab Report forwarding:** The System must provide the ability to recognize CMRs and Lab Reports (manually entered or electronically received) that properly belong to a non-participating jurisdiction (NPJ), and forward them electronically to the correct NPJ by messaging (to those NPJ's capable of receiving HL7 messages) or via automated fax server (to those NPJ's unable to receive HL7 messages.) Note: For information about the Electronic Laboratory Reporting project, please see *ELR-Business-Requirements.doc*.
D	**N**	**1.6.1.2**	**CMR receiving**: The System must provide the ability to receive CMR messages forwarded from separate NPJ systems utilizing current PHIN/CalPHIN message specifications.
D	**N**	**1.6.1.3**	**Case investigation transfers:** The System must provide the ability to support the transfer of in-progress case investigations/case files (and related case responsibility) to separate systems capable of receiving such transfers electronically, by Fax, or other mechanism. The System must provide the ability to receive the standard case investigation transfer format.
D	**N**	**1.6.1.4**	**Contact investigation transfers:** The System must provide the ability to support the delegation of a contact investigation to a separate NPJ system capable of receiving such transfers electronically, by Fax, or other mechanism. The system shall also be capable of receiving the standard contact investigation transfer format.
D	**N**	**1.6.1.5**	**Transfer acceptance notifications:** The System must provide the ability to inform the originating jurisdiction when the transferred data has been received by the destination LHD and responsibility for the transferred case/contact investigation has been accepted.
O	**N**	**1.6.1.6**	**Post-transfer information forwarding:** When the system receives additional information for a case that has already been transferred, that information should be forwarded to the new jurisdiction. The System must provide the ability to notify the new jurisdiction that additional information has been received.
D	**N**	**1.6.1.7**	**Case/contact investigation sharing:** The System must provide the ability to support sending case/contact investigation information to separate NPJ systems for informational/sharing purposes only (i.e. responsibility for the investigation remains with the sending jurisdiction.) Should also be able to send within system.
D	**Y**	**1.6.1.8**	**Local-to-State case reports**: The System must provide the ability to receive provisional case reports (from separate NPJ systems) for cases still under investigation (for aberration detection), and receive updates, and final case reports (for review and counting) utilizing current PHIN/CalPHIN message specifications.

1.6.1 Integration Requirements			
Rank	**Demo**	**Req ID**	**Description**
D	**N**	**1.6.1.9**	**State-to-Local case report feedback:** The System must provide the ability to provide feedback to NPJ systems when certain conditions are or are not met (example incomplete information or inconsistent with case definition)—whether triggered automatically by logic process or manually by a state case reviewer.
D	**N**	**1.6.1.10**	**Inter-jurisdictional outbreak report:** The System must provide the ability to inform another (State or local) jurisdiction of a suspected or confirmed outbreak, including high-level summary information such as the number of cases and the data range of the outbreak.
D	**N**	**1.6.1.11**	**Enable external interaction with Master Person Index:** The System must provide appropriate interfacing to allow all jurisdictions (participating or not) to access a statewide MPI. Access to include functions for searching for existing entries, viewing likely matches, selecting a match or submitting a new person addition request and retrieving the centrally assigned identifier for inclusion in case messages such as Local-to-State case report s.
D	**Y**	**1.6.1.12**	**Audit Log:** The System must be able to audit any forwarded CMRs, Lab Reports, and transferred case reports to NPJs. (Status assignment for transfers will be “Transfer”.)

1.7 System Documentation

The system needs to be appropriately documented, come with a full set of documentation, and include any specifications pertinent to California’s installation of the system.

1.7.1 System Documentation Requirements			
Rank	**Demo**	**Req ID**	**Description**
M	**N**	**1.7.1.1**	Contractor to deliver system documentation at the conclusion of initial installation and deployment of the system, including any specifications pertinent to California’s installation of the system. The documentation should also include an overview of system logic with clearly described input parameters, batch programs and process models. To include hard copy reference materials, CD and/or other electronic format.

1.7.1 System Documentation Requirements			
Rank	**Demo**	**Req ID**	**Description**
M	**N**	**1.7.1.2**	Contractor shall provide a complete logical and data model of the application. The model should represent all application classes, attributes and their associations. If there are explicit data types or a reference to a list of data elements and stored value domains available, these should be provided (electronically) as well. The model can be in the form of an entity-relationship diagram (e.g. data or implementation model) or preferably a UML representation (e.g. logical model) if available. Electronic copies are required and minimally sufficient, but a hardcopy representation would be ideal as well. If a UML model(s) is available, it should be provided in electronic form in a standard application agnostic format (e.g. an XML file). **Note**: This requirement is essential to allow for a full understanding of how data is represented with in the application. It is clearly expected that no single vendor can provide all the processing needs for CDHS now or in the future and the ability to expose or consume information within the solution between other applications (e.g. API's) is a fundamental criterion. If desired, CDHS and the vendor may engage in a reciprocal confidentiality or non-disclosure agreement before this level of detail is shared or exchanged, but this is not required.
M	**N**	**1.7.1.3**	Vendor will provide the following System Documentation with the necessary updates made to address CDHS' requirements : • System Administration manual • System Configuration/Implementation Manual • System Architecture To include hard copy reference materials, CD and/or other electronic format. All system documentation must be updated with each new release, when appropriate.

1.8 Training

There are various needs for training while the System is being implemented. Three levels of training are anticipated, one geared towards technical support staff, one geared towards help desk staff and trainers, and one geared towards end users. Training is expected to take place on-site and in conjunction with system installations.

Training for support staff

Training is planned to cover the following. Training for system technical support staff includes system administrators, data analysts, and infrastructure support staff.

- Technical training for technical system administrators and DBAs. (On site - Sacramento)
- Training for business oriented System Administrators and Data analysts. (On site – Sacramento, Richmond)
- End-use-oriented training for 2nd line support, trainers and some pilot participants. (On site – Sacramento, Richmond)

1.8.1 Training Requirements			
Rank	**Demo**	**Req ID**	**Description**
D	**N**	**1.8.1.1**	Vendor must provide initial training for technical support staff to include system administrators, data analysts, and infrastructure support staff. Describe how this training would be conducted; include number and length of training sessions, number of people in each session, and description of materials provided.
D	**N**	**1.8.1.2**	Vendor must provide initial training for help desk and trainers include help desk support staff, trainers, and system administrators. Describe how this training would be conducted; include number and length of training sessions, number of people in each session, and description of materials provided.
D	**Y**	**1.8.1.3**	Vendor to provide end-user training materials, including web-based and online self-paced modules (e-learning instructional designs and formats) based on CDHS' workflow and business needs. Describe what types of material you provide, in what format and media types. Include target audience for each material listed. To include hard copy reference materials, CD and/or other electronic format.
D	**Y**	**1.8.1.4**	Vendor to allow the State to customize the training materials. Describe in what way we would be able to customize the material and what types of materials we would be able to customize.
D	**N**	**1.8.1.5**	Vendor must provide knowledge transfer training for technical support staff to include system administrators during the installation and configuration phases of the implementation. This knowledge transfer session must cover the installation of software and configuration of web-forms. Describe how this knowledge transfer would occur; include number and length of sessions, number of people in each session, and description of materials provided.

1.9 Conversion of Existing Data

The System should be able to electronically populate the System with initial data from some existing systems. Initially, some operational data for cases under investigation, or recently under investigation in local health department systems may need to be migrated into the transactional data store.

It is anticipated that historical data for cases previously reported to the State will be migrated to a statewide analytic data store; these data will be migrated from various CDHS data sets. However, this section addresses the migration requirement, not the actual system architecture. The number of records and the complexity of the data will vary. For 2005 there were roughly 260,000 disease events reported, with around 230,000 of these being relatively simple morbidity reports—the remainder being more complex case-reports. For the period of 1990 to the present there are roughly 2.3 million morbidity records representing roughly 3.1 million cases (there are roughly 53,000 summary records which represent either outbreaks or weekly case counts by disease and jurisdiction).

1.9.1 Data Conversion Requirements			
Rank	**Demo**	**Req ID**	**Description**
D	**N**	**1.9.1.1**	Vendor will develop migration plan for DCDC and branches/programs and Local Health Departments and will migrate required data into system based on branch mapping guidelines.

<table>
<tr><th colspan="4">1.9.1 Data Conversion Requirements</th></tr>
<tr><th>Rank</th><th>Demo</th><th>Req ID</th><th>Description</th></tr>
<tr><td>D</td><td>N</td><td>1.9.1.2</td><td>
Existing TB Databases: Must be able to migrate TIMS legacy data from TIMS local and state systems into new Web-based application database. Mandatory to include TB legacy data 1993 to current (post-TIMS). Desirable to include TB legacy data 1985 to 1992 (pre-TIMS). Must also include TIMS User-defined-Fields data from the TBCB Registry and LHDs with local TIMS systems.
TBCB needs migration of approximately 50,000 TIMS records (and preferably an additional 34,000 records for the 1985-1992 periods.
TBCB requires that existing TB data from the following databases be migrated:
<table>
<tr><th>Record Categories</th><th>Database</th><th># of Records</th></tr>
<tr><td>RVCT</td><td>TIMS</td><td>50,000</td></tr>
<tr><td>A/B-Notification</td><td>ACCESS</td><td>30,000</td></tr>
<tr><td>ARPE</td><td>ACCESS</td><td>800</td></tr>
<tr><td>MDR-TB</td><td>ACCESS</td><td>400</td></tr>
<tr><td>Genotyping</td><td>ACCESS</td><td>3,500</td></tr>
<tr><td>Other Registry dbs (e.g.: moved cases)</td><td>ACCESS</td><td>8,000</td></tr>
<tr><td>Legacy data for patients with multiple FU-2 will be migrated and linked with surveillance data for that case.</td><td></td><td></td></tr>
<tr><td>LHD migration of UDFs: LHDs should be able to migrate their local User Defined Fields (UDFs) into the RVCT form. The RVCT form will contain an additional section at the end of the form for local UDFs.</td><td></td><td></td></tr>
</table>
</td></tr>
</table>

<table>
<tr><th colspan="4">1.9.1 Data Conversion Requirements</th></tr>
<tr><th>Rank</th><th>Demo</th><th>Req ID</th><th>Description</th></tr>
<tr><td>D</td><td>N</td><td>1.9.1.3</td><td>Existing Vaccine-preventable Disease databases: Must be able to migrate IZB legacy data from the following databases:
<table>
<tr><th>Record Categories</th><th>Database</th><th># of Records</th></tr>
<tr><td>Pertussis</td><td>SAS</td><td>18,000</td></tr>
<tr><td>Measles</td><td>SAS</td><td>21,000</td></tr>
<tr><td>Rubella</td><td>SAS</td><td></td></tr>
<tr><td>Invasive Haemophilus influenzae</td><td>SAS/Access</td><td>3,200</td></tr>
<tr><td>Tetanus</td><td>SAS</td><td>200</td></tr>
<tr><td>Acute Hepatitis B</td><td>SAS</td><td>25,000</td></tr>
<tr><td>Hepatitis A</td><td>SAS</td><td>70,000</td></tr>
<tr><td>Perinatal Hepatitis B (cases)</td><td>SAS/Excel</td><td>750</td></tr>
<tr><td>Meningococcal disease</td><td>SAS/Access</td><td></td></tr>
<tr><td>Varicella deaths</td><td>Excel</td><td></td></tr>
<tr><td>Varicella (hospitalized cases)</td><td>Excel</td><td></td></tr>
<tr><td>Mumps</td><td>Access/Excel</td><td>2,700</td></tr>
<tr><td>Perinatal Hep B case management</td><td>SAS</td><td>65,000</td></tr>
<tr><td>Diphtheria</td><td>Excel</td><td></td></tr>
<tr><td>Poliomyelitis</td><td>Excel</td><td></td></tr>
<tr><td>Chronic Hepatitis B registry</td><td>TBD</td><td>(100,000)</td></tr>
</table></td></tr>
</table>

<table>
<tr><th colspan="4">1.9.1 Data Conversion Requirements</th></tr>
<tr><th>Rank</th><th>Demo</th><th>Req ID</th><th>Description</th></tr>
<tr><td>D</td><td>N</td><td>1.9.1.4</td><td>Existing STD Databases: Must be able to migrate STD legacy data from the following databases:
<table>
<tr><th>Record Categories</th><th>Database</th><th># of Records</th></tr>
<tr><td>CA STD Morb (line list and summary case data files)</td><td>EpiInfo</td><td>Line list – 1,306,000
Summary – 49,107 records for 873,907 cases</td></tr>
<tr><td>CA Syphilis IR</td><td>EpiInfo</td><td>14,000</td></tr>
<tr><td>CDC Field Record</td><td>EpiInfo</td><td>Demographics – 116,000
Disposition – 120,000</td></tr>
<tr><td>Syphilis Reactor</td><td>EpiInfo</td><td>Demographics – 125,000
Tests – 283,000 records with 1-2 tests per record</td></tr>
<tr><td>CA Congenital Syphilis Worksheet</td><td>EpiInfo</td><td>3,300</td></tr>
<tr><td>CDC Congenital Syphilis Case Investigation Report</td><td>EpiInfo</td><td>4,100</td></tr>
<tr><td>CA LGV Suspected Case Form</td><td>MS Access</td><td>160</td></tr>
</table></td></tr>
</table>

<table>
<tr><th colspan="4">1.9.1 Data Conversion Requirements</th></tr>
<tr><th>Rank</th><th>Demo</th><th>Req ID</th><th>Description</th></tr>
<tr><td>D</td><td>N</td><td>1.9.1.5</td><td>IDB existing data conversion categories and approximate number of records to migrate to analytical data warehouse:
<table>
<tr><th>Record Categories</th><th># of Records</th></tr>
<tr><td>IDB1: are conditions specifically listed on the WMPR which are not handled by other Branches, excluding chronic hep c (approximately 61 categories).</td><td>525,000</td></tr>
<tr><td>IDB2: other 17CCR2500 conditions managed by IDB (approximately 24 additional categories).</td><td>15,000</td></tr>
<tr><td>IDB3: Chronic Hepatitis C (or earlier chronic Non-A, Non-B reports) for the purposes of creating a registry.</td><td>350,000</td></tr>
</table></td></tr>
<tr><td>O</td><td>N</td><td>1.9.1.6</td><td>Existing Animal Rabies Database to analytical data warehouse.</td></tr>
<tr><td>O</td><td>N</td><td>1.9.1.7</td><td>Existing Food borne Disease Outbreak Database to analytical data warehouse.</td></tr>
<tr><td>D</td><td>N</td><td>1.9.1.8</td><td>Existing General morbidity database to analytical data warehouse.</td></tr>
<tr><td>D</td><td>N</td><td>1.9.1.9</td><td>Existing Local disease reporting databases to analytical data warehouse.</td></tr>
</table>

1.10 Technical Support

1.10.1 Technical Support Requirements			
Rank	**Demo**	**Req ID**	**Description**
M	**N**	**1.10.1.1**	Vendor to provide ongoing technical support for system administrators and Help Desk staff.
M	**N**	**1.10.1.2**	Vendor to support multiple methods of technical support requests, such as email, phone, fax, etc. Vendor must describe the methods of contact that are offered for the product.
M	**N**	**1.10.1.3**	Vendor to provide technical support Monday thru Friday, 8:00 AM to 5:00 PM PST in accordance with the State of California holiday schedule.
M	**N**	**1.10.1.4**	Vendor to prioritize technical support calls and address them in priority order. Minimal response times should be in associated with type of priority. Priority type should also consider whether a call is a support questions or product defect. Vendor must describe how they ensure timely and competent support.
M	**N**	**1.10.1.5**	Vendor to provide emergency support 7/24/365 in addition to the standard technical support.

1.11 System Maintenance / Upgrades

1.11.1 System Maintenance and Upgrade Requirements			
Rank	**Demo**	**Req ID**	**Description**
M	**N**	**1.11.1.1**	Vendor to provide timely system updates as needed to conform to PHIN certification and other relevant CDC standards. Include description of how vendor stays abreast of standards and certification information.
M	**N**	**1.11.1.2**	Vendor to provide version control of the system. Vendor to describe their change management process.
M	**N**	**1.11.1.3**	Vendor to provide periodic system updates and maintenance releases to update technology and address user suggestions. Vendor must describe their historical release cycle and plans for the future.
M	**N**	**1.11.1.4**	Vendor must assure that system configuration is maintained during upgrades and maintenance releases. Application must remain stable and data is not overwritten. Application configuration must remain stable.
M	**N**	**1.11.1.5**	Vendor must provide proof of regression testing prior to implementation of a new release, to ensure that system has not been negatively affected by the upgrades.

2 Business Requirements

2.1 Web-based Application Interface

2.1.1 Graphical User Interface Requirements			
Rank	**Demo**	**Req ID**	**Description**
D	**Y**	**2.1.1.1**	The System must provide a web interface ("Provider Portal") that is separate from the State/LHD web interface for providers to manually enter new *California CMR reports* into the System. The interface must be specifically targeted to the providers and must be simple, intuitive, and convenient. 2FA is not required for provider login.
M	**Y**	**2.1.1.2**	The System must provide a web-based application interface for LHD and State.
M	**Y**	**2.1.1.3**	Application usability design must comply with Federal Government Section 508 laws. Under Section 508 (29 U.S.C. '794d), agencies must give disabled employees and members of the public access to information that is comparable to the access available to others. The law applies to all Federal agencies when they develop, procure, maintain, or use electronic and information technology. See http://www.section508.gov/. The State of California requires 508 compliance on State Government websites. See http://www.cio.ca.gov/IOUCARecommendations.html.
M	**Y**	**2.1.1.4**	The System must be designed to adhere to web interface and application designs standards and best practices as set forth by the State of California. **Application Standards**: The web-based application design must provide user-friendly, uncluttered data entry screens, easily understood error, edit, and confirmation messages, and user-friendly navigation between functions. The application must be 508 compliant (see Requirement # 2.1.1.3, above). CDHS will provide the vendor with appropriate State of California Department of Health Services application standards and best practices as specified by the CDHS ITSD group. **Website Standards**: While not strictly pertaining to a web-based application (as opposed to a website), website standards are provided here as a point of reference and should be a consideration of the web-based application design. California standards that should be used in the planning of new and redesigned state websites are found at http://www.cio.ca.gov/IOUCARecommendations.html.
M	**Y**	**2.1.1.5**	The System must provide context-specific dynamic forms where only necessary fields appear on the screens. For instance, when reporting a disease, only fields applicable to that disease should be visible.

2.1.1 Graphical User Interface Requirements			
Rank	**Demo**	**Req ID**	**Description**
M	**Y**	**2.1.1.6**	The System must provide the ability to designate all required fields for data entry throughout the application. For users with the appropriate security permission, the System must provide the ability to configure and designate required fields based on defined business rules.
O	**Y**	**2.1.1.7**	Electronic forms must have standard state-of-the-art “look and feel” on the Web page to support ease of data entry, data retrieval, and data updating/correction. CDHS will provide the vendor with appropriate State of California Department of Health Services application standards and best practices as specified by the CDHS ITSD group. Also see requirements 2.1.1.3 and 2.1.1.4, above.
M	**Y**	**2.1.1.8**	The web-based CMR form must provide a method of uniquely identifying to the user the entity or domain responsible for that report. This should minimally include prominent identifiers or labels as follows: 1) A short text description about the entity the report will be sent to located in the body "<body></body>" section and at the top (e.g. header) portion of the page. This text can also be a hyperlink that connects the user back to the home page of that jurisdiction where local information (e.g. jurisdiction-specific reportable conditions) will be made available. It should also use a consistent naming convention or style yet to be described (e.g. California CMR: San Joaquin County). 2) This could also include a "breadcrumb" division element within the page such as "California WebCMR > Sacramento County >". 3) An explicit title located in the title "<title></title>" section of the web document describing the same information as in #1 above. This is especially important if the user decides to print the report for hardcopy storage because the title section of a web document persists in the printed page. 4) A jurisdiction logo may be used. It should be optimized to be compliant with application guidelines or a style guide (e.g. appropriate image file type, image dimensions, rules regarding use of image transparency, etc.)

2.1.2 Help and User Assistance Requirements			
Rank	**Demo**	**Req ID**	**Description**
M	**Y**	**2.1.2.1**	**Help for Provider Level**: The System must provide a provider-specific online Help feature on the Provider Level to assist providers with CMR data entry.

2.1.2 Help and User Assistance Requirements			
Rank	**Demo**	**Req ID**	**Description**
M	**Y**	**2.1.2.2**	**Help for form fill-in**: There should be a Help button on each form page. The topic should be sensitive to the page context. There should be a method (click on question number or title) to display field-level help for each question on the form. **Note**: TBCB has standalone Help for RVCT forms (TB Registry Guidelines) in MS Help, HTML Help, and/or PDF formats.
M	**Y**	**2.1.2.3**	**Application Help**: The System must provide online help functionality for all web pages in the application. This Help system (as differentiated from the Form Fill-In Help) should provide general application help, such as how-to and navigation assistance for the user.
D	**Y**	**2.1.2.4**	**Context-sensitive Help**: The System must provide context-sensitive help functionality
D	**Y**	**2.1.2.5**	**Administrator Help**: The System must provide a specialized Help system for State and LHD Administrators (how to add users, modify user information, change passwords, run administrative reports, etc.).
O	**N**	**2.1.2.6**	**Help configurable**: The System must allow for help topics to be configurable. Describe how the System help can be configurable, to what level, and by whom (vendor or CDHS Administrator).
M	**Y**	**2.1.2.7**	**Reference Information and links**: The System (including Provider Level) must provide the configurable ability to link to instructional materials for program information, references on procedures, diseases, and other business related materials, including intervention and treatment protocols.

2.2 Data Input

2.2.1 Electronic Laboratory Reporting (ELR) Data Input Requirements			
Rank	**Demo**	**Req ID**	**Description**
M	**Y**	**2.2.1.1**	The System must match and link all accepted laboratory reports, whether they are submitted via manual entry or via an unsolicited ELR report, to its associated case when first captured, if such cases exist. If no matching case exists, the system should automatically create a new case and link the lab report to the new case. New system-proposed linkages and cases should be flagged or queued for review by the responsible jurisdiction**.**

2.2.1 Electronic Laboratory Reporting (ELR) Data Input Requirements			
Rank	**Demo**	**Req ID**	**Description**
M	**Y**	**2.2.1.2**	The System must match and link all accepted laboratory reports, whether they are submitted via manual entry or via an unsolicited ELR report, to its associated case when first captured, or immediately after initiation of a CMR case if the case is created after the receipt of the ELR message. The System should provide for a provisional case on receipt of an ELR report that is unable to be matched to an existing case so that CMR users may assign the report to a case if there are problems in creating a match, if the laboratory report requires an immediate response, the ELR message should be used to initiate a case or to keep the message in a queue for processing later when a case is created. In any event, all unassigned ELR messages should be flagged for review after a predetermined time to close them and remove them from the queue as needed.

2.2.2 Provider Data Input Requirements			
Rank	**Demo**	**Req ID**	**Description**
D	**Y**	**2.2.2.1**	The System CMR entry form fields should closely resemble the current version of the California CMR form at the time of application release. The vendor should provide a prototype of the form for approval by the CDHS. The form should be intuitive and easy to use. It could incorporate controls such as tabs, buttons, menus, toolbars, and icons.
D	**Y**	**2.2.2.2**	The disease identifier should be standardized for notifiable diseases in alphabetical order with sub-groups (nested sort) for specific diseases. The “drop-down” list of reportable conditions should be designed to be easy and intuitive, based on ITSD standards, for providers or their representatives to use, including in particular listing conditions by logical disease group rather than strictly alphabetically—for example “primary syphilis”, “secondary syphilis”, “latent syphilis“, and “syphilis – unknown stage” should all be listed under “syphilis”, not alphabetically under “p”, “s”, “l” , and “s” etc.

2.2.2 Provider Data Input Requirements			
Rank	**Demo**	**Req ID**	**Description**
D	**Y**	**2.2.2.3**	For user entry of disease conditions or syndromes of public health interest, the system should display to the user a constrained list of options and limit the availability of free-text entries unless there is a compelling reason, such as when the user needs to report in an ad-hoc fashion, a condition or event that falls outside the scope of current legislation or common practice. The following provides the recommended workflow for entry of such information: 1. The user is first presented with a list that only enumerates reportable diseases and conditions as indicated by current legislation (i.e. Title 17, Section 2500). 2. If the condition of interest is not covered by this value domain, the system would then allow the user to next select from an alternative list with a value set of additional diseases or conditions that are emerging or perhaps locally reportable (e.g. such as methicillin-resistant staphylococcus aureus or respiratory syncytial virus). 3. If this second option was not sufficient, the system would then present to the user a free-text entry option. Because the system would be unable to understand the semantic meaning and sense of urgency of a free-text entry, the system would minimally provide two fields; the first would be a short disease or condition entry option that briefly describes the issue followed by a separate field for a more detailed description or explanation with pertinent findings, notes, contact information, etc. A third option could be an option to assign the acuity or severity about the event being reported.
D	**Y**	**2.2.2.4**	The System must provide the ability for providers and reporters to add/attach electronic documents to a CMR report, including Lab reports. The System should provide (Level 2) additional metadata elements for attachments as *options*. These metadata elements would be based on a published document metadata standard such as Dublin Core (DCMI). Suggested DCMI terms for inclusion are: • *Title* • *Identifier* (a UID auto generated by the system) • *Relation* (reference to source CMR) • *Format* (data or MIME type such as “jpg”, “PDF”) • *Description* • *Date Issued* (auto generated) The system should then index the CMR and attachment based on this metadata so it may be more readily searched or queried.

2.2.2 Provider Data Input Requirements			
Rank	**Demo**	**Req ID**	**Description**
D	**Y**	**2.2.2.5**	The System to incorporate business rules for form validation for providers without having to interact with the 2FA. This will include error checks such as: • Valid value for variables • Mandatory variables • Consistency across variables • Date sequence
D	**Y**	**2.2.2.6**	The System must record the date and time original case notification from healthcare provider was submitted to LHD through CMR completed online (critical). This date should be available in the database for export and report display.
D	**Y**	**2.2.2.7**	The System must assign a unique ID number for each CMR submitted.
D	**Y**	**2.2.2.8**	The System must provide confirmation of successful submission of reports and display the system-assigned unique ID number for the CMR and the assigned jurisdiction.
O	**N**	**2.2.2.9**	The System must provide the ability to create multiple reports if two or more conditions are reported on a single CMR, without having to duplicate data entry for each condition.
D	**Y**	**2.2.2.10**	Specific data element issues: • Ability to manually enter a person's age if date of birth is unknown. Field should permit value entry in months, days, and years. The units used should be indicated as discrete values. • Ability to identify provider type (HIV clinic, STD clinic, HMO, PP/FP, etc.) in all provider reports; ability to link provider with provider type based on provider registry table.
D	**Y**	**2.2.2.11**	The System must provide the ability to display/capture common lab test names when manually capturing lab reports, as an alternative to LOINC and SNOMED codes.

2.2.2 Provider Data Input Requirements			
Rank	**Demo**	**Req ID**	**Description**
O	**N**	**2.2.2.12**	The System must provide the ability for providers with the appropriate authentications and permissions to do the following: • Location of existing/previously entered reports • Viewing of reports submitted by lab and providers for their associated patients. • Printing of reports and update these. • Find and read information about what to report and when. • Some provider functions may require secure access that extends beyond a simple sign-on.

2.2.3 Local Health Department and State Data Input Requirements			
Rank	**Demo**	**Req ID**	**Description**
M	**Y**	**2.2.3.1**	The System must provide the ability for local health departments and/or the state health department to enter event data into the System including CMR, lab data and disease-specific case form data.
M	**Y**	**2.2.3.2**	The System must enforce search of person index when attempting to create a new case. If the person already exists (the same person, diagnosis etc), system should indicate that the case exists and display identifying information, including the jurisdiction responsible for that case.
D	**Y**	**2.2.3.3**	The WYSIWYG appearance of electronic forms on the Web page should be congruent with paper versions of forms. The general order within a section must be the same as the paper form.

2.2.3 Local Health Department and State Data Input Requirements			
Rank	**Demo**	**Req ID**	**Description**
D	**Y**	**2.2.3.4**	**List of IZB Case Report Forms** • Congenital Rubella Syndrome (CDC 71.17) • Diphtheria (DHS 8579, revised 01/99) • Haemophilus influenzae, invasive disease (DHS-PM 401) • Hepatitis A, Acute (CDC form and DHS 8556) • Hepatitis B, Acute (CDC form) • Hepatitis B, Perinatal (CDC form) • Measles/Rubeola (DHS 8345) • Meningococcal Infections (DHS 8469) • Mumps (DHS 8690) • Perinatal Hepatitis B Case Management Report Form (DHS 8546) • **Pertussis (DHS 8258) [DEMO]** • Poliomyelitis (DHS 8421) • Rubella (German Measles) (PM 358) • Tetanus (CDC Appendix 18 – to be revised in 2007) • Other outbreaks (DHS 8554) = used by all programs • Varicella (Chickenpox) (DHS 8299 and CDC form) • Varicella Death (CDC)

2.2.3 Local Health Department and State Data Input Requirements			
Rank	**Demo**	**Req ID**	**Description**
D	**Y**	**2.2.3.5**	**List of IZB forms for collecting additional information in special situations** (outbreak forms; contact management forms; disease-specific questionnaires for food borne hepatitis A outbreak, CRS case, etc.) • Pertussis death worksheet (CDC) • Tetanus – Illegal drug use questionnaire • Food borne outbreak questionnaire for hepatitis A (to be developed) • School measles outbreak control school audit form • School measles outbreak control summary of school immunization record audit • **Contact follow-up sheet for meningococcal disease (DHS) [DEMO]** • Contact follow-up sheet for pertussis (to be developed) • Contact follow-up sheet for measles (DHS 8345) • Contact follow-up sheet for varicella (to be developed) • Contact follow-up sheet for rubella (PM 358) • Congenital rubella syndrome maternal questionnaire (DHS) • Congenital rubella syndrome chart review form (DHS) • DASH laboratory form (CDC) • Smallpox forms (CDC)
D	**Y**	**2.2.3.6**	**List of STD Required Forms**: • **California Syphilis Interview Record (CA IR V23 – 2/14/2005) [DEMO]** • CDC Field Record (CDC 73.2936S Rev 5/01) • Gonorrhea Case Investigation Record (GC IR V2 – 12/2006) • Congenital Syphilis Case Investigation Worksheet (Rev 1/2004) • CDC Congenital Syphilis (CS) Case Investigation and Report (CDC 73.126 Rev 10-2003) • California Neurosyphilis Case Investigation Form (CA Neuro V1.5 –2/2007) • CDC/California Lymphogranuloma Venereum (LGV) Suspected Case Report Form (CDC/CA LGV V4 – 2/7/2005)

2.2.3 Local Health Department and State Data Input Requirements			
Rank	**Demo**	**Req ID**	**Description**
D	**Y**	**2.2.3.7**	**List of IDB Forms** • Anthrax • Botulism • Brucellosis • **E.coli 0157 [DEMO]** • Food borne Outbreak form • Hepatitis C • Legionellosis • Lyme Disease • Qfever • Salmonellosis • Tularemia • Typhoid Fever • Typhoid Carrier • Unusual Disease Form • Vibrio / Cholera • WNV • General Outbreak - Norovirus 1 • General Outbreak - Norovirus 2 • General Outbreak - Respiratory 1 • General Outbreak - Respiratory 2 • General Outbreak - Other disease • General Outbreak - Healthcare Facility

2.2.3 Local Health Department and State Data Input Requirements			
Rank	**Demo**	**Req ID**	**Description**
			• Hantavirus • Leptospirosis • Listeriosis • Malaria • Plague • Rabies - Human • RMSF / Typhus • SARS • Toxic Shock Syndrome • Trichinosis • Waterborne Disease Outbreak • Dengue • Psittacosis • Kawasaki • Yellow Fever **List of VRDL Forms** • West Nile Virus (WNV) Infection Case Report
D	**Y**	**2.2.3.8**	**List of TB required forms**: **TB case report forms** • **RVCT Report – Report of Verified Case of Tuberculosis/ DHS 8620 A (1/03) [DEMO]** • **Follow Up-1 Report - Initial Drug Susceptibility Report/ DHS 8620 B (10/00) [DEMO]** • **Follow Up-2 Report – Case Completion Report/ DHS 8620 C (10/00) [DEMO]**

2.2.3 Local Health Department and State Data Input Requirements			
Rank	**Demo**	**Req ID**	**Description**

			• MDR-TB Report (Multi-drug Resistant TB)
			• MDR-TB checklist
			TB B notification for immigrants and refugees
			• Electronic Disease Notification (EDN) US based TB Evaluation Worksheet
			• A/B-Notification Report – Report of Alien with Tuberculosis (CDC 75-17)
			• A/B-Notification Report of Sentinel Event/ TBCB/CDHS Version 2
			• Hmong ATS Classification Worksheet/ 10/31/05 version 2
			TB Outbreak reporting
			• Outbreak Report – In revision 12/2006
			TB Contact reporting and targeted testing
			• Aggregate Report for Program Evaluation – Contact Investigation (ARPE-CI) – Preliminary/ DHS 8635 A (08/03)
			• ARPE CI Report – Final/ DHS8635 B (08/03)
			• TB Case Contact Roster (CIF December 2004)
			• TB Contact Information Form (CIF December 2004)
			• ARPE Contact Report Data Tallying Tool/ CDHS TBCB (12/03)
			• ARPE Targeted Testing and Treatment for LTBI/ CDC
			• Contact Investigation Toolkit
			  • CI-Case-Contact-Roster.pdf
			  • CI-Case-Data-Dictionary.pdf
			  • CI-Comparison-table-data-elements.pdf
			  • CI-Contact-Data-Dictionary.pdf
			  • CI-Contact-Info-Form.pdf
			  • CI-Data-Variables-List.pdf

2.2.3 Local Health Department and State Data Input Requirements			
Rank	**Demo**	**Req ID**	**Description**
			• CI-Plan-Implement-CI-Improvement-Project.pdf (INFO) • CI-Policies-Procedures.pdf (INFO) • CI-Using-Data-To-Improve.pdf (INFO) • CI-Using-Data-To-Improve-Staff-Processes.pdf **Additional forms used by LHDs:** • Forms for use with patients who move during TB treatment • Interjurisdictional Tuberculosis Notification (ITN)/ NTCA 3/2002 • Interjurisdictional TB Notification (ITN) Follow-up/ NTCA 5-2002 • Cure TB Bi-national Notification/ HHSA: DC-50 (08/02) County of San Diego HHS • CDC International TB Notification Form/ revised 22 Feb. 2000 • Immigration and Customs Enforcement (ICE) Notification of TB (form in revision)
D	**Y**	**2.2.3.9**	**TB requirements for Follow Up-2 Case Completion Report**: • There must be the ability to capture more than one Case Completion Report - Follow-up 2 form per case of TB. • Only one FU-2 form, the most recently submitted (non-administrative) FU-2 will be transmitted to the CDC. • A user with the appropriate permissions should be able to instantiate an administrative FU-2 form on behalf of a local user, or to fill a TBCB Registry need.
M	**Y**	**2.2.3.10**	The System must provide the ability to add CMRs for a patient reported with multiple conditions on a single CMR, without having to duplicate data entry for each condition.
M	**Y**	**2.2.3.11**	Specific data element issues: • Ability to manually enter a person's age if date of birth is unknown. Field should permit value entry in months, days, and years. The units used should be indicated as discrete values. • Ability to identify provider type (HIV clinic, STD clinic, HMO, PP/FP, etc.) in all provider reports; ability to link provider with provider type based on provider registry table.
M	**Y**	**2.2.3.12**	The System must provide the ability to display/capture common lab test names when manually capturing lab reports, as an alternative to LOINC and SNOMED codes.

2.2.3 Local Health Department and State Data Input Requirements			
Rank	**Demo**	**Req ID**	**Description**
D	**Y**	**2.2.3.13**	The disease identifier should be standardized for notifiable diseases in alphabetical order with sub-groups (nested sort) for specific diseases. The “drop-down” list of reportable conditions should be designed to be easy and intuitive, based on ITSD standards, for providers or their representatives to use, including in particular listing conditions by logical disease group rather than strictly alphabetically—for example “primary syphilis”, “secondary syphilis”, “latent syphilis“, and “syphilis – unknown stage” should all be listed under “syphilis”, not alphabetically under “p”, “s”, “l” , and “s” etc.
M	**Y**	**2.2.3.14**	For user entry of disease conditions or syndromes of public health interest, the system should display to the user a constrained list of options and limit the availability of free-text entries unless there is a compelling reason, such as when the user needs to report in an ad-hoc fashion, a condition or event that falls outside the scope of current legislation or common practice. The following provides the recommended workflow for entry of such information: 1. The user is first presented with a list that only enumerates reportable diseases and conditions as indicated by current legislation (i.e. Title 17, Section 2500). 2. If the condition of interest is not covered by this value domain, the system would then allow the user to next select from an alternative list with a value set of additional diseases or conditions that are emerging or perhaps locally reportable (e.g. such as methicillin-resistant staphylococcus aureus or respiratory syncytial virus). 3. If this second option was not sufficient, the system would then present to the user a free-text entry option. Because the system would be unable to understand the semantic meaning and sense of urgency of a free-text entry, the system would minimally provide two fields; the first would be a short disease or condition entry option that briefly describes the issue followed by a separate field for a more detailed description or explanation with pertinent findings, notes, contact information, etc. A third option could be an option to assign the acuity or severity about the event being reported.
D	**Y**	**2.2.3.15**	The System must record the date and time the original disease notification was submitted from healthcare provider to LHD by phone. • For diseases that are mandated to be reported by phone immediately or within 24 hours the system should support collection of the date and time the phone notification was received • This data could be collected when a healthcare provider submits a CMR online following the call (ideally there is a reminder message displayed when the provider selects the option to report a CMR online for a disease that must be reported by phone immediately or within 24 hours) • This data could be collected from LHD that received a phone notification

2.2.3 Local Health Department and State Data Input Requirements			
Rank	**Demo**	**Req ID**	**Description**
D	**Y**	**2.2.3.16**	The System must provide the ability for users to add/attach electronic documents to a CMR report, including Lab reports. Additionally, the System should provide (Level 2) additional metadata elements for attachments as *options*. These metadata elements would be based on a published document metadata standard such as Dublin Core (DCMI). Suggested DCMI terms for inclusion are: • *Title* • *Identifier* (a UID auto generated by the system) • *Relation* (reference to source CMR) • *Format* (data or MIME type such as “jpg”, “PDF”) • *Description* • *Date Issued* (auto generated) The system should then index the CMR and attachment based on this metadata so it may be more readily searched or queried.
M	**Y**	**2.2.3.17**	The System must provide the ability to allow forms to be saved before completing/submitting it.
M	**Y**	**2.2.3.18**	The System must provide the ability to allow a user the choice to save or clear changes to data on a screen.
M	**Y**	**2.2.3.19**	The System must provide the ability to prevent the loss of entered data, such as auto-save functions, alerts to the user if a form is closed without saving, etc.
M	**Y**	**2.2.3.20**	The System must provide action-specific confirmation messages such as “Are you sure you want to delete this record?” System should prompt user when making changes that are irreversible.
M	**Y**	**2.2.3.21**	The System must provide the ability to allow merging the data from different sources (lab, provider) into one report according to rules governing the disease, form, and branch.
M	**Y**	**2.2.3.22**	The System must pre-fill case report/management forms with CMR and lab report data with existing information where appropriate.

2.2.3 Local Health Department and State Data Input Requirements			
Rank	**Demo**	**Req ID**	**Description**
M	**Y**	**2.2.3.23**	The System must perform a range (regarding complexity) of data validation processes. These range from rather simple dynamic client-side data type checking to more complex validation tasks based on business rules as categorized in more granular requirements enumerated below. To do this effectively the application should use a layered validation methodology so that form validation (e.g. web interface client-sided field validation), business rule validation (e.g. rule logic separately maintained in a rules engine) and persistence (e.g. server-sided, state or transaction data persistence) are cleanly separated. This is essential to separate data from application logic and to allow for more efficient and reliable maintenance of rules, centralization of rule logic and to permit the use of separate tools for creation if required. Additionally, client-sided dynamic validation shall remain in compliance with W3C (World Wide Web Consortium) standards and shall not be dependent upon browser specific proprietary technologies (e.g. Microsoft ActiveX).
M	**Y**	**2.2.3.24**	**Meta-validation**: Meta-validation determines if all required data elements have been successfully submitted and that no forbidden data has been included in the submission. The scope may be within a single form or across multiple forms.
M	**Y**	**2.2.3.25**	**Syntactic validation**: This involves form field checks where data types (e.g. text, binary, MIME-type), data structure or pattern (e.g. email address, telephone numbers), data length (e.g. character limit) or data size (e.g. file size) are constrained via a boundary are validated.
M	**Y**	**2.2.3.26**	**Semantic validation**: This level of validation requires concurrent evaluation of other dependent fields, such as matching gender or age in a demographic form with a specific condition, comparing disease acuity with date of onset, comparing a laboratory observation with the scale, specimen source or methodology expected, or comparing user reported age with date of birth for example.
M	**Y**	**2.2.3.27**	**Domain validation**: Domain validation requires linkage or reference to a knowledge base or other reference that is independent of the form document being validated. Therefore this is ostensibly a method of semantic validation as described above, but in a broader or higher level construct. It requires interaction with domain specific information residing outside the scope or focus of the current form. Examples include the matching of an entered laboratory test with the associated disease condition. This specific test represented on entry may be encoded within a structured vocabulary such as LOINC, but the LOINC code does not match exactly with the expected LOINC code or is not within an enumerated list of codes expected for that condition. To mitigate this, a more complex association of tests to conditions using an entity relationship or ontology, would be leveraged for this level of validation. Therefore validation of values against a value domain or against associations or relationships to values one or more nodes removed from that value domain would be used, but requires a greater level of complexity regarding algorithms, forward or backward chaining logic, a knowledgebase, etc.

2.2.3 Local Health Department and State Data Input Requirements			
Rank	**Demo**	**Req ID**	**Description**
M	**Y**	**2.2.3.28**	The System must provide the following error checking and field validations for forms: **Form Fields**: The forms should have built-in error checking for standard form errors such as verification of character data and format in numeric, alpha, and date fields, as well as form-specific field validations and missing information in required fields as specified in other validation requirements in this section. **Validation Rules**: When the user submits the form (or page if the form is spread over more than one page), the data submitted is validated according to the form validation rules. The application must provide confirmation of success or fail. If fail, error messages must be displayed that inform the user of the error and provide instructions for correcting it. If successful, the next appropriate page in the form creating/edit workflow should be displayed. **Error Messages**: The validation error messages occur when a user is entering data in an online form and an action results in an "error" condition in the field check by the validation engine. Validation error messages must also be provided in the Web Services (or data exchange) report submission response message. Also applies to batch transmission of reports.

2.3 Data Viewing, Editing, and Deleting

2.3.1 Data Viewing and Editing Requirements			
Rank	**Demo**	**Req ID**	**Description**
M	**Y**	**2.3.1.1**	**View**: For users with the appropriate security permission, the System must provide the ability to view individual case reports and other surveillance reports. The data displayed in the report would depend on the user's sign-on permissions.
M	**Y**	**2.3.1.2**	**Edit**: For users with the appropriate security permission, the System must provide the ability to edit previously entered individual case reports and other surveillance reports. Certain conditions would apply as well as restrictions based on the user's sign-on permissions.
M	**Y**	**2.3.1.3**	**Delete**: For users with the appropriate security permission, the System must provide the ability to delete cases.

2.3.1 Data Viewing and Editing Requirements			
Rank	**Demo**	**Req ID**	**Description**
D	**Y**	**2.3.1.4**	For users with the appropriate security permission, the System must provide the ability to simultaneously view all cases assigned to them, across jurisdictions (so they do not have to log on to each jurisdiction's Web-CMR portal to see their assignments for that jurisdiction). **Note**: This should also support the EIP role.

2.4 Case Processing

2.4.1 Case Assignment and De-duplication Requirements			
Rank	**Demo**	**Req ID**	**Description**
M	**Y**	**2.4.1.1**	The System must automatically assign CMR reports and lab reports to the correct jurisdiction based on: 1) geocode of the patient's address, 2) patient's City, 3) geocode address of the provider, or 4) provider's City.
M	**Y**	**2.4.1.2**	The System must provide the ability to manually reconcile duplicate reports, cases, and persons.
D	**Y**	**2.4.1.3**	The System must provide the ability to visually compare (side-by-side or top-to-bottom) cases/reports to each other (such as CMR to case, case to case, lab reports to cases) (*e.g.* by allowing multiple records to be viewed at the same time).

2.4.2 Case Identification and Confirmation Requirements			
Rank	**Demo**	**Req ID**	**Description**
M	**Y**	**2.4.2.1**	The System must provide the ability to automatically associate and link multiple disease-specific reports such as CMRs, Case Reports, Lab reports, and field records to an individual case. **IZB criteria**: jurisdiction, disease, last name, first name, gender, date of birth.
M	**Y**	**2.4.2.2**	The System must provide the ability to manually associate and link multiple disease-specific reports such as CMRs, Case Reports, Lab reports, and field records to an individual case.

2.4.2 Case Identification and Confirmation Requirements			
Rank	**Demo**	**Req ID**	**Description**
M	**Y**	**2.4.2.3**	The System must provide the ability to set, modify, and weight criteria for automatically linking disease-specific reports to individual cases. Ability for manual review and modification by LHD of automatic links should be available. For example, the criteria for CMR matching might be: Jurisdiction, disease, last name, first name, sex, DOB, Specimen Collection Date, and Diagnosis Date. **Note**: For less than 100% match, the System will provide the ability for DCDC branches to review and change or add own disease-specific criteria. **TBCB**: TBCB will provide algorithm (based on patient name, jurisdiction, date of birth, sex, status of current TB case (if present), and date of specimen collection) to determine whether a new CMR or ELR should create a new case or be linked to an existing case. LHD should have the ability to manually review, and confirm or reject, the results of the algorithm. **STDCB's matching criteria**: For 100% match, the System will make a comparison if the difference between the Specimen Collection Data and the Diagnosis Date is less than or equal to 31 days. **Diseases**: Chlamydia, Chlamydial PID, Gonorrhea, Gonococcal PID **Incoming report, exact match, and variable**: Lab to Lab - Jurisdiction, disease, last name, first name, sex, - DOB Specimen collection dates within 30 days CMR to CMR - Jurisdiction, disease, last name, first name, sex, - DOB Diagnosis dates within 30 days CMR to Lab - Jurisdiction, disease, last name, first name, sex, - DOB Specimen collection and diagnosis dates within 30 days Lab to Case -Jurisdiction, disease, last name, first name, sex, - DOB Specimen Collection date within 30 days of the specimen collection or diagnosis date found in the case CMR to Case - Jurisdiction, disease, last name, first name, sex, - DOB Diagnosis date within 30 days of the specimen collection or diagnosis date found in the case
M	**Y**	**2.4.2.4**	The System must provide the ability to associate and link multiple cases (both confirmed or suspect cases) to a single person. Should also be able to link a person to multiple cases.
M	**Y**	**2.4.2.5**	The System must automatically link appropriate forms and task lists to the case based on the specified disease. Programs will provide disease-specific business rules for linking forms and task lists to the case reports.
M	**Y**	**2.4.2.6**	The System must provide the ability to ensure that patient demographic information on a case report form is forever linked to that specific case and cannot be automatically be overwritten by subsequent cases or report forms.

2.4.2 Case Identification and Confirmation Requirements			
Rank	**Demo**	**Req ID**	**Description**
M	**Y**	**2.4.2.7**	The System must provide the ability to identify and record cases which are “epi-linked”.
D	**N**	**2.4.2.8**	TB Case Verification Requirements: • There should be a “Case Verification and Count Date” page that appears when the user has submitted the RVCT form. The page confirms the RVCT entry and displays the result of the Vercrit calculation which determines if the report qualifies and can be counted as a verified case of tuberculosis (see CDC documentation for Case Verification Criteria in the *TIMS Surveillance Import Utility* in **Appendix C**). • If the report qualified, the user can enter a count date and save the report. If it did not qualify, the user may save the report as "suspect" (to be counted later), or override the “suspect” status with "Provider diagnosis" to count the case. The TB Case Registry sends both suspect and counted cases to the CDC, however the CDC only reports counted cases (not suspect). The TB Case Registry does strive to resolve suspect case prior to transmitting to the CDC. • The Vercrit calculation must be performed and result returned to the user for both direct data entry online and via web-services/data exchange methodology.
D	**N**	**2.4.2.9**	The System must provide the ability to allow prioritization of cases both automatically and manually (such as high, medium and low per disease condition). The user with the appropriate role will be able to override the system prioritization.
D	**Y**	**2.4.2.10**	The System must provide the ability to prioritize contacts. Examples of priorities are: High, medium, low.

2.4.2 Case Identification and Confirmation Requirements			
Rank	**Demo**	**Req ID**	**Description**
M	**Y**	**2.4.2.11**	The System must provide the ability to allow assignment of both an LHD and State case confirmation status. If State case status differs from LHD case status, the LHD should be notified. Case status is dependent upon disease-specific case definitions and may include but is not limited to the CDC-provided categories as shown below. System should permit case status to be changed when updated with new information. The System should display categories based on the disease. **Note**: See the **Glossary of Terms**, *Case Classification* entry in this document for status definitions. • Clinically compatible case • Confirmed case • Epidemiologically linked case • Laboratory-confirmed case • Probable case • Supportive or presumptive laboratory results • Suspected case Not on CDC list, but may be useful for Web-CMR: • Unknown • Not classified • Not a case **Note**: These classifications are not generally used for Tuberculosis (see 2.4.2.15 for TB ATS classifications, and 2.4.2.8 for TB validation process (see CDC documentation for Case Verification Criteria in the *TIMS Surveillance Import Utility* in **Appendix C**). **Note**: The laboratory or clinical criteria for a specific disease are defined by CDC in "Case Definitions for Infectious Conditions Under Public Health Surveillance" http://www.cdc.gov/epo/dphsi/casedef/index.htm. For most conditions, a person must meet the case definition to be a countable case. **For additional links, see**: the Glossary entry for *Case Classification* and *Case Definition*.

2.4.2 Case Identification and Confirmation Requirements			
Rank	**Demo**	**Req ID**	**Description**
M	**Y**	**2.4.2.12**	The System must provide the ability to allow change in the LHD investigation status of a case. LHD Investigative Status levels for cases at a minimum would include the following status categories: • Open = State or local health department has received the case • Closed = Activities with this case is completed, It should be able to close the case even if data is missing. Status categories will be established during configuration phase of application implementation.
M	**Y**	**2.4.2.13**	In addition to the LHD investigation status categories identified in business requirement 2.4.2.12 that are configured during application implementation, the system will include a workflow investigation status. This investigation status allows LHD to develop new workflows, or update existing ones, with locally configured status levels for individual programs such as Perinatal Hep-B. The list of workflow status levels is a superset of all the possible workflow steps of interest to all participating LHDs. The superset enables each LHD to select the steps that they want to track.
M	**Y**	**2.4.2.14**	The System must provide the ability to capture information related to closing of case including treatment completion, reason for closing of case, transfer of patient, and administrative closure.
D	**Y**	**2.4.2.15**	The System must provide the ability to allow the assignment (or re-assignment) of TB status per the American Thoracic Society (ATS) classification of TB Status (1-5). Reference: Am J Respir Crit Care Med. 2000 Apr; 161(4 Pt 1):1376-95. Many LHD prioritize activities and funding based on the ATS classification. • Class 0: No TB Exposure • Class 1: TB exposure, No evidence of infection • Class 2: TB infection, No disease • Class 3: TB, clinically active+ • Class 4: TB, not clinically active • Class 5: TB suspected **Note**: This requirement is related to 2.4.2.11.

2.4.2 Case Identification and Confirmation Requirements			
Rank	**Demo**	**Req ID**	**Description**
D	**N**	**2.4.2.16**	The System must provide the ability to identify missing reports (such as CMR or lab report that has not been received from the provider or lab). Since most cases should be reported both from the lab and from a provider there is a need to identify missing reports (*e.g.,* when only a lab report was received for a disease that should be reported from both, or when only a clinical report was received when a lab report was expected).
D	**N**	**2.4.2.17**	The System must provide the ability to identify if reports that have been specified as required (such as case reports) are missing from a case.

2.4.3 STD Syphilis Reactor System Requirements			
Rank	**Demo**	**Req ID**	**Description**
D	**N**	**2.4.3.1**	The System must provide the ability to assign priority in the syphilis reactor grid based on business rules using the following parameters: patient age, gender, non-treponemal serologic test titer, zip code or census tract, type of provider (e.g., HIV clinic provider always coded as a priority 1
D	**N**	**2.4.3.2**	The System must provide the ability to manually add historical syphilis test, treatment and diagnosis data for cases being investigated, in particular, previous history from other states/countries
D	**N**	**2.4.3.3**	The System must provide the ability to change gridding parameters at state and local level
D	**N**	**2.4.3.4**	The System must provide the ability to automatically prioritize incoming syphilis lab tests for follow-up based on simple reactor “gridding” rules and populate a dedicated “priority” field with the resultant priority value. This field must be retained and associated with the laboratory test.
D	**N**	**2.4.3.5**	The System must provide a second “priority” field for manual entry based on review of relevant data by knowledgeable staff. This field must also be retained and associated with the laboratory test. Both the automated and manual fields are required for proper follow-up assignment and evaluation.
D	**N**	**2.4.3.6**	The System must provide the ability to migrate historical reactor registry into new system for referencing in reactor grid assignments

2.4.3 STD Syphilis Reactor System Requirements			
Rank	**Demo**	**Req ID**	**Description**
D	**Y**	**2.4.3.7**	System must provide the ability to have a summary screen view, for a selected person, of the person's name, most recent address, sex, DOB, all historical syphilis tests (including the requesting provider, specimen collection date, test type and results), treatment history (including treatment, treating provider, and date treatment began), and diagnoses (including diagnosis and date diagnosed).

2.4.4 Case Registry Requirements			
Rank	**Demo**	**Req ID**	**Description**
D	**Y**	**2.4.4.1**	The System should provide the ability to create and maintain basic disease or condition-centric *registry* functions. The registry should encompass uniform data elements relating to patient morbidity and associated clinical information. It may include disease-specific laboratory information as well laboratory data relating to co-morbidities, case investigation including status, patient care information, and patient outcomes. The registry should be centered around a defined set of disease or condition case criteria. The scope of these registry requirements covers communicable diseases, with current focus on hepatitis B and C, typhoid carriers, tuberculosis, and syphilis (covered in STD Syphilis Reactor System requirements in this document). The System should also provide registry functions that enable users to view all data associated with an individual patient (patient-centric) as described in disease-specific requirements in this section.
O	**Y**	**2.4.4.2**	**Registry Data Summary**: The system should provide summary data to include the following (not inclusive): • Registry inclusion criteria. • Case definition or reference to namespace/URI where a standard case definition is stored (e.g. CDC). • Description of all registry metadata including short/long name, full description, associated question text (if there is a separate registry application), data type, data length, value domain if the data element is enumerated, where the data is used (e.g. which registries), creation date and last revision date. • Number of cases represented. • Summary statistics including incidence and prevalence. • Distribution (across time and geographic regions) of confirmed or probable cases (if appropriate).

2.4.4 Case Registry Requirements			
Rank	**Demo**	**Req ID**	**Description**
D	**Y**	**2.4.4.3**	The System must provide the ability to export the data elements associated with each disease registry in formats as defined in the Export requirements in this document.
D	**N**	**2.4.4.4**	**Disease-Specific Requirements for:** **Hepatitis B:** Data elements that are expected for capture and retrieval through predefined or ad-hoc queries within the registry and that are expected to be produced in a summary screen view will come from various data sources including: **1. Current CMR/AVSS** Demographic information for patient: Name (patient and provider), age or date of birth, gender, race, ethnicity, primary residence, occupation, contact information (patient and provider Other info from existing CMR form (date of onset; date diagnosed; date of death) Pregnant, EDD Occupation LHD case classification (from AVSS): Acute, Chronic or Perinatal **2. Revised CMR Form variables** Signs and symptoms data Reason for test Liver function test dates and results Lab results Diagnosis (checked on CMR form) **3. Case Form variables** Clinical data Reason for test Lab test results Liver function test dates and results Diagnosis (checked on case form) Patient history data (exposures, risk factors, vaccination hx) Previous hepatitis lab test results

2.4.4 Case Registry Requirements			
Rank	**Demo**	**Req ID**	**Description**
			4. Lab variables: including specimen collect date, test result, test result date and requesting provider for the following: • Total anti-HAV (total antibody to hepatitis A virus) • HBsAg (hepatitis B surface antigen) • Total anti-HBc (total antibody to hepatitis B core antigen) • IgM Anti-HBc (IgM antibody to hepatitis B core antigen) • Anti-HBs (antibody to hepatitis B surface antigen) • HBeAg (hepatitis B "e" antigen) • Anti-HBe (antibody to hepatitis B "e" antigen) • HBV DNA • Anti-HDV (antibody to hepatitis D virus) • Anti-HEV (antibody to hepatitis E virus)

2.4.4 Case Registry Requirements			
Rank	**Demo**	**Req ID**	**Description**
D	**N**	**2.4.4.5**	**Disease-Specific Requirements for:** **Hepatitis C** Data elements that are expected for capture and retrieval through predefined or ad-hoc queries within the registry include: name (patient and provider), age or date of birth, gender, race, ethnicity, primary residence, place of birth, occupation, contact information (patient and provider), date of diagnosis, disease staging information (i.e. acute, chronic or other staging criteria), case investigation status (i.e. confirmed, probable, suspect, etc.) concurrent active problems or co-morbidities (if available), and cause of death (if available). **Laboratory Information**: • Enzyme immunoassay (EIA) with signal to cut-off ratio (s/co) predictive of a true positive as defined by CDC. • Chemiluminescence (CIA) index value predictive of a true positive as defined by CDC. • Recombinant immunoblot assay (RIBA) if available. • Nucleic acid test (NAT) with RNA if available. • Hepatitis genotype if available.

2.4.4 Case Registry Requirements			
Rank	**Demo**	**Req ID**	**Description**
D	**N**	**2.4.4.6**	**Typhoid Carrier** The System should support a typhoid carrier registry function or view. This registry is intended to capture important information regarding the status of patients who have been identified as typhoid carriers for tracking and monitoring (i.e., patient view), as well as for summary statistics (i.e., view across all carriers). Minimum data elements required for typhoid carrier registry functionality are listed below. The System will use existing data elements in WebCMR whenever available to assemble the registry view, and will allow manual entry of elements unique to this registry. • **Patient Information**: Full patient name, alias (if available), gender, race, age, ethnicity, place of birth, occupation, occupational history, current residence and current patient communication information including contact phone number(s) as well as patient change of residence history. • **Travel History**: Travel history should be included describing specific locations and dates of travel as well as the route of travel (if available). • **Patient Test History**: Temporal storage or serialization of all related laboratory tests, including stool or urine tests for *Salmonella typhi* with test type, date of analysis, observation, interpretation; specimen type (e.g., stool or urine); and ordering clinician or provider. • **Treatment History**: Treatment history should include all treatments (or untreated); type of therapy (e.g. antibiotics); and treatment dates. • **Carrier Status**: A summary of carrier status history including any history of typhoid fever, carrier type (convalescent or chronic; fecal, urinary, or other), and any previous history form other states/countries. The System must be able to generate reminders to public health staff every six months to check and update the carrier status of patients in the registry.

2.4.4 Case Registry Requirements			
Rank	**Demo**	**Req ID**	**Description**
D	**N**	**2.4.4.7**	**Tuberculosis** The System must provide the ability to search, retrieve, view, and export all counted TB cases (as defined by CDC and CDHS counting criteria) as well as RVCT and user-defined data elements, providing a functional TB case registry for data queries. These TB criteria are documented in the ***TIMS Surveillance Import Utility.pdf*** and TB Data Dictionary in Appendix A. **TB MDR sub-registry**: For all culture positive TB cases (counted or not) that are resistant to Isoniazid and Rifampin (on any laboratory report and/or RVCT (F/U-1 or F/U-2)), the System must provide the ability to retrieve RVCT, laboratory, and genotyping data. The System must also provide the ability to view, query and export this data. • Laboratory susceptibility testing and genotyping data must be linked to the case's RVCT (when available) and must include: collection dates, sub-culture dates, submission dates, date received at MDL, test method, isolate type, submitting lab, accession/laboratory numbers, drug susceptibility results, molecular beacon results, culture identification, spoligotype, miru, PCR, RFLP, cluster name, IS6110_fingerprint, IS6110_band_no, PCR/RFLP cluster. • System must provide the ability to add and remove data elements from the above list.
D	**Y**	**2.4.4.8**	The System must use published case definitions to identify data elements required for disease-specific registry functions.
D	**Y**	**2.4.4.9**	The System must use specific inclusion criteria (in addition to case definitions) to determine if cases and/or associated reports should be included in a disease-specific registry.

2.4.5 Case Management (Evaluate, Treat, and Monitor) Requirements			
Rank	**Demo**	**Req ID**	**Description**
D	**Y**	**2.4.5.1**	The System must provide the ability to assign an investigator or a team of investigators to a case.
D	**Y**	**2.4.5.2**	The System must provide the ability to permit the assignment of staff for the evaluation, treatment and follow-up of a patient.

2.4.5 Case Management (Evaluate, Treat, and Monitor) Requirements			
Rank	**Demo**	**Req ID**	**Description**
D	**N**	**2.4.5.3**	The System must provide the ability to support the following methods for assignment of STD investigations in regional and local offices: Round Robin, Investigator-of-the-Day Method, Investigator-per-Condition Method, Geographically assigned, Manually assigned
O	**Y**	**2.4.5.4**	The System must provide the ability to send referrals to other agencies. In its simplest form this could be the ability to generate and print paper referrals. *Related to system's ability to communicate with external entities*.
D	**Y**	**2.4.5.5**	The System must provide the ability to capture and track incentives and enablers provided to patient to improve adherence to treatment. Typical incentives and enablers include provision of housing assistance, transportation tokens/tickets, food vouchers, etc.
D	**Y**	**2.4.5.6**	The System must record the calendar time and when and whether anticipated key treatment benchmarks been met. Specific benchmarks indicating treatment progress include: conversion to negative bacteriology, acquisition of drug resistance, improvement in other clinical markers, calculation of medication received, updates from external providers. The System must provide the ability to flag certain sentinel results or events requiring immediate attention (MDR-TB, default, etc.) (See Notifications section).
O	**N**	**2.4.5.7**	The System must provide the ability to, based on the classification of the patient, provide a template for standard TB care plans that can be configured to the patient. Template should include: • Patient contact, Intake and assessment • Treatment regimen and duration • Calendar of appointments • Agreements/contracts between LHD and case; • Provision of Directly Observed Therapy (DOT), clarity on the role of the HD • Establishment and communication of care plan for TB patients receiving primary care outside the health department (e.g. hospital, private provider, correctional facility, etc) • Referrals to outside providers and services • Treatment Education and prevention information

2.4.5 Case Management (Evaluate, Treat, and Monitor) Requirements			
Rank	**Demo**	**Req ID**	**Description**
D	**N**	**2.4.5.8**	The System must provide the ability to capture information about legal actions taken towards a patient. System to capture whether legal action is taken with patient. Typical legal actions can include orders for 1) Examination, 2) TB Treatment, 3) Directly Observed Therapy, 4) Isolation, 5) Detention, and 6) Incarceration. System to provide templates. Legal references for forms necessary to initiate legal actions. System to provide ability to associate notes, legal process/escalation steps, etc related to legal action.
O	**N**	**2.4.5.9**	The System must provide the ability to capture household information on a patient/contact form.
D	**Y**	**2.4.5.10**	The System must provide the ability to allow for two way communication between LHD and CDHS regarding case report form data (completeness, consistency, case definition).
D	**Y**	**2.4.5.11**	For users with the appropriate security permission, the System must provide the ability to: open, close, reopen, create, modify, save, delete, undelete, and view a case investigation.
D	**Y**	**2.4.5.12**	For users (local and regional managers) with the appropriate security permission, the System must provide the ability to assign, reassign, and monitor case management tasks and ability to review and modify data across jurisdictions. • ability for supervisors to review investigations • ability for supervisors to approve or reject closed investigations or change the case status
D	**Y**	**2.4.5.13**	The System must provide the ability to generate a field record.
D	**Y**	**2.4.5.14**	The System must provide the ability to automatically display/include disease-specific task lists based on disease being investigated.
O	**N**	**2.4.5.15**	The System must provide the ability to randomly sample cases for additional interview or follow-up.

2.4.5 Case Management (Evaluate, Treat, and Monitor) Requirements			
Rank	**Demo**	**Req ID**	**Description**
D	**N**	**2.4.5.16**	The System must provide the ability to facilitate the case management of infants born to HBsAg+ women (see Perinatal Hepatitis B Prevention Program report form). The System must provide the ability to link chronic / carrier to others (person defined as carrier, related to multiple persons / cases). For example, carrier (mother) entered as case, infant entered and managed as contact. The system must provide the ability to import case-report form data for the Perinatal Hep B program that is sent electronically to the state from LHDs.
D	**Y**	**2.4.5.17**	The System must provide the ability to capture all relevant information needed to complete the RVCT and Follow-up forms in the System Patient Management module.
D	**Y**	**2.4.5.18**	The System must provide the ability for the collection of risk factors for non adherence to treatment. (see Related under Track Enablers and Legal Action)
D	**Y**	**2.4.5.19**	The System must provide the ability for the collection of information on risk factors for transmission and infection control (e.g. is isolation required, etc)
D	**Y**	**2.4.5.20**	The System must provide the ability to present all information pertinent to the writing of orders for care: e.g. a consolidated view of the information in Enrollment, Classification, History, Care Plan, and Risk Assessment.
D	**Y**	**2.4.5.21**	The System must provide the ability to capture all anti-tuberculosis drugs prescribed to patient including any subsequent changes to drug regimen.
D	**Y**	**2.4.5.22**	The System must provide the ability to track duration of drug regimen and summarize amount of medication taken and the number of months and weeks on treatment and the number of doses taken of each drug.
D	**Y**	**2.4.5.23**	The System must provide the ability to capture whether therapy is administered by DOT, track DOT visits and results of DOT (i.e. patient was observed taking medication, patient absent/missing, patient refused, drug delivered, but not observed, etc).
D	**Y**	**2.4.5.24**	The System must provide the ability to capture standard tests for TB evaluation, treatment and monitoring included but not limited to radiology reports, tuberculin skin tests, blood assays for TB infection, and bacteriology.
D	**Y**	**2.4.5.25**	The System must provide the ability to capture whether ordered tests were obtained.

2.4.5 Case Management (Evaluate, Treat, and Monitor) Requirements			
Rank	**Demo**	**Req ID**	**Description**
D	**Y**	**2.4.5.26**	The System must provide the ability to capture specimen collection (i.e., date, type, etc.)
D	**Y**	**2.4.5.27**	The System must provide the ability to capture status of submitted specimens.
D	**Y**	**2.4.5.28**	The System must provide the ability to capture the results and any updates to ordered tests either electronically through ELR/StarLIMS or direct data entry.
D	**Y**	**2.4.5.29**	The System must provide the ability to capture a series of tests (i.e. repeated, multiple tests) per patient.
D	**Y**	**2.4.5.30**	In addition to medication and specimen collection, system should permit capture of other information reflecting treatment progress. Specific examples include: • Adverse drug reactions. • Changes in care status (i.e. change in provider or assigned LHD staff) • Change in care facility (i.e. discharge from hospital or other care facility, release from corrections) • Change in patient residence, job, home environment. Other life events potentially disruptive to TB treatment (travel, substance abuse, etc).
D	**Y**	**2.4.5.31**	The System must provide the ability for users to add/attach electronic documents to a Case report/event such as a PDF or jpeg.

2.4.6 Transfer and Sharing of Cases and Contacts Requirements			
Rank	**Demo**	**Req ID**	**Description**
M	**Y**	**2.4.6.1**	The System must provide the ability to allow transfer of cases between jurisdictions. When a case is transferred all history should be maintained.
M	**Y**	**2.4.6.2**	The System must provide the ability for the originating jurisdiction to view the original case management reports after reassignment to the destination jurisdiction.
M	**Y**	**2.4.6.3**	The System must provide an acknowledgement of the transfer (reassignment) to the originating jurisdiction. The acknowledgement must provide a confirmation of receipt and acceptance or rejection of the transfer.
M	**Y**	**2.4.6.4**	The System must provide the ability to enter multiple RVCT Follow-up 2s (Case Completion Reports) on TB cases that transfer between jurisdictions prior to treatment completion. The FU2s will be entered by each jurisdiction involved in the care of the patient.
D	**Y**	**2.4.6.5**	All RVCT Follow-up 2s (Case Completion Reports) of TB cases who transfer between jurisdictions prior to completion of treatment will be viewable by all jurisdictions that were part of the case's history and to TBCB Registry staff.
M	**Y**	**2.4.6.6**	The System must provide the ability to share a case between jurisdictions for case management. Primary jurisdiction has read-write capability; secondary jurisdiction has read capability only.
M	**Y**	**2.4.6.7**	The System must provide the ability to assign cases/reports/clients to the correct jurisdiction.
M	**Y**	**2.4.6.8**	The System must provide the ability to allow an originating jurisdiction to reassign case management reports to other (destination) jurisdictions.

2.4.7 TB MDR Data Requirements

Most of the requirements for MDR will be met by the inclusion of 1) drug susceptibility results in ELR interfacing with StarLIMS, 2) by linking ELR and StarLIMS results with the Patient Registry, and the Web-CMR and RVCT records/data, and 3) including MDR as an alert for LHD and state.

Rank	Demo	Req ID	Description
D	Y	2.4.7.1	The System must provide the ability to ensure all drug susceptibility data elements are captured from ELR requirements.
D	Y	2.4.7.2	The System must provide the ability to receive susceptibility results and allow viewing by LHDs and State users.

2.4.8 TB Genotyping Data and Forms Requirements

Most of the requirements for genotyping will be met by 1) the inclusion of genotyping results in ELR interfacing with StarLIMS, 2) by linking ELR and StarLIMS results with the Patient Registry, and the Web-CMR and RVCT records/data, and 3) by notifying LHD and TBCB when genotyping results are available.

Rank	Demo	Req ID	Description
D	Y	2.4.8.1	The System must provide the ability to ensure that all genotyping data elements are captured from ELR inputs.
D	Y	2.4.8.2	The System must provide the ability to receive genotyping results and allow viewing by LHDs and State users.
D	Y	2.4.8.3	For users with the appropriate security permission (LHD, MDL and TBCB), the System must provide the ability to share genotyping results in the event of misrouted data, patient movement, outbreaks, and data sharing agreements between regional partners.
D	N	2.4.8.4	The System must provide the ability to migrate legacy genotyping data.
D	Y	2.4.8.5	The System must provide the ability to define newly developed laboratory diagnostics and to receive the results from the new diagnostics.

2.4.9 TB A/B-Notification and Sentinel Events			
The A/B-Notification is a form sent to the TBCB from a Local Health Jurisdiction who has received an immigrant alien classified with Class A or Class B1 TB (typically Class B).			
Rank	**Demo**	**Req ID**	**Description**
D	**N**	**2.4.9.1**	The System must provide the ability to interface with the CDC's Electronic Data Network (EDN) when it becomes operational (e.g., receive uploads of data from EDN).

2.5 Contact Investigation and Follow-up

2.5.1 Contact Identification, Notification, Evaluation, Treatment, and Monitoring Requirements			
Rank	**Demo**	**Req ID**	**Description**
D	**Y**	**2.5.1.1**	The System must provide the ability to allow the capture of minimal contact information on generic and disease-specific forms. The DCDC branches shall provide disease/branch specific contact data collection requirements and form requirements in separate appendices. These are data elements for current and potential forms (provided in data dictionary format). The contact information may be initially provided by field reports, xxxx, xxxx, and laboratory results. Note: A "Contact" may be a person, place, location, animal, or other. Make separate requirement
D	**Y**	**2.5.1.2**	The System must provide the ability to generate a list of contacts that require additional follow up based on contact priorities. **For example**: system would have the capacity to prioritize contacts for follow-up (e.g., prophylaxis and/or quarantine) using disease-specific rules developed by IZB (e.g., post-exposure prophylaxis of infants < 6 mos who have been exposed to pertussis = high priority contact; pregnant woman exposed to varicella = high priority contact).
D	**Y**	**2.5.1.3**	The System must provide the ability to generate and/or link to letters to be sent to case contacts notifying them that they may have been exposed, etc. with additional information as appropriate about the disease, prophylaxis, etc.
D	**N**	**2.5.1.4**	The System must provide the ability to attach/add documents to contacts. See attachment requirements in State and LHD Data Entry section.
D	**Y**	**2.5.1.5**	The System must provide links between cases and contacts and between contacts and sources/index cases.

2.5.1 Contact Identification, Notification, Evaluation, Treatment, and Monitoring Requirements			
Rank	**Demo**	**Req ID**	**Description**
D	**Y**	**2.5.1.6**	In the event that a contact becomes a case, the System must allow this transition while maintaining all history on the contact and not require duplicate data entry.
D	**Y**	**2.5.1.7**	The System must provide the ability to apply a status to contacts. Status categories will be established during configuration phase of application implementation. For example, potential status assignments could be: • Possible Contact: contact names, but exposure status not yet verified • Contact of Interest: contact identified, and follow up is needed • Close contact • Casual contact • Not classified as a contact • Confirmed contact
D	**Y**	**2.5.1.8**	The System must provide the ability to prioritize contacts. Examples of priorities are: High, medium, low.
D	**Y**	**2.5.1.9**	The System must provide the ability to apply an investigation status for contacts. Status categories will be established during configuration phase of application implementation.
D	**Y**	**2.5.1.10**	The System must provide the ability to assign staff (investigator or nurse, etc) responsible for locating, evaluating, monitoring and treating the located contact.
D	**Y**	**2.5.1.11**	The System must provide the ability for transferring contacts and sharing of data on contacts between local users and between local health jurisdictions.
D	**Y**	**2.5.1.12**	The System must provide the ability for the assignment of a jurisdiction to a contact. As a default the assignment should be based on the contact's address (if known), and possible to change manually
O	**N**	**2.5.1.13**	The System must provide the ability to include visual social network analysis tool.

2.5.2 ARPE (Aggregate Reports for Program Evaluation) Requirements

ARPE Data Entry, Data Capture, Validation Requirements, Report Calculations, Data Import, Display, Export Requirements, ARPE Notification Requirements (Note: The ARPE report has the same direct and electronic data entry requirements as the RVCT report, with the following additional requirements)

Rank	Demo	Req ID	Description
D	**N**	**2.5.2.1**	The System must provide the ability to capture the ARPE form by any one of the following methods: • Online data entry in the Web-CMR application. • Pre-population from pertinent data in the Application database (this may be from RVCT, Contact Investigation forms, or other related forms). • Data exchange transmissions from LHDs with their own patient management/surveillance systems.
D	**N**	**2.5.2.2**	The System must provide the ability to pre-populate the Preliminary and Final ARPE reports for each LHD using the pertinent data captured from semi-annual cohorts of TB cases. The data can be drawn from other case-related reports such as RVCT and contact rosters or contact tallying reports.
D	**N**	**2.5.2.3**	The System must provide the ability to pre-populate the Final ARPE form (the pre-populated data should be editable by the user) with data from the related Preliminary ARPE form.
D	**N**	**2.5.2.4**	The submission of 'No Contacts to Report' will be automated, user will click one button and have zeros ('0') populate the form.
D	**N**	**2.5.2.5**	The System must provide the ability to capture California specific fields, but will exclude these identified fields for export to the CDC.
D	**N**	**2.5.2.6**	The System must provide the ability to validate data entry of ARPE form fields based on validation rules (TBCB will provide validation rules).
D	**N**	**2.5.2.7**	The System must provide the ability to sum individual Preliminary and Final ARPE reports across LHDs and calculated for the state of California.
D	**N**	**2.5.2.8**	The TB Contact Roster form will be available for direct data entry of pertinent information on contacts needed to populate the ARPE (see TB Contact Roster form, Appendix C).
D	**N**	**2.5.2.9**	The TB Contact Tallying form will be available for direct data entry of pertinent information on contacts needed to populate the ARPE (see TB Contact Tallying form, Appendix C).
D	**N**	**2.5.2.10**	"Part II. Evaluation Indices" will be calculated for the user from data entered in "Part 1 Cases and Contacts".

2.5.2 ARPE (Aggregate Reports for Program Evaluation) Requirements			
ARPE Data Entry, Data Capture, Validation Requirements, Report Calculations, Data Import, Display, Export Requirements, ARPE Notification Requirements (Note: The ARPE report has the same direct and electronic data entry requirements as the RVCT report, with the following additional requirements)			
Rank	**Demo**	**Req ID**	**Description**
D	**N**	**2.5.2.11**	Legacy ARPE data will be migrated to the web-based application.
D	**N**	**2.5.2.12**	The System must provide the ability to display a report that shows all RVCT cases that comprise the semi-annual cohort for inclusion in the ARPE report.
D	**N**	**2.5.2.13**	The System must provide the ability to export the ARPE data.
O	**N**	**2.5.2.14**	The System must provide the ability to trigger Notifications for reminders for ARPE submission and for newly submitted ARPE reports. Notifications are based on the ARPE Schedule for Reporting Contacts to TB Cases in California.

2.6 Outbreak Management and Investigation

2.6.1 Outbreak Management and Investigation Requirements			
Rank	**Demo**	**Req ID**	**Description**
D	**N**	**2.6.1.1**	The System must provide a comprehensive, integrated case/outbreak management system (1) to coordinate the identification and follow-up of (a) possible sources of infection of VPD cases and (b) contacts of infectious VPD case(s) and (2) to coordinate interventions to prevent or control the further spread of VPDs (e.g., perinatal hepatitis B case management)
D	**N**	**2.6.1.2**	The System must provide the ability to assign an outbreak confirmation status. (Example, outbreak status could be Probable, Suspected outbreak, confirmed outbreak, low outbreak probability (rule out situation).)
D	**Y**	**2.6.1.3**	The System must provide the ability to review all outbreaks with/by certain statuses, outbreaks in specific jurisdictions, etc.

2.6.1 Outbreak Management and Investigation Requirements			
Rank	**Demo**	**Req ID**	**Description**
D	**Y**	**2.6.1.4**	The System must provide the ability for the creation of outbreak episodes in the System. Information collected about outbreaks could be: identifier/outbreak name, jurisdiction, investigator, investigation status, contact info, risk factors, outbreak status, etc.
D	**Y**	**2.6.1.5**	The System must provide the ability to receive disease notification, including notification to create a new case or outbreak record or notification to update an existing case or outbreak record
D	**Y**	**2.6.1.6**	The System must provide the ability to share outbreak information with all jurisdictions with cases, contacts, or locations involved in the investigation.
D	**N**	**2.6.1.7**	The System must provide the ability to add additional information to an outbreak including adding/attaching electronic documents.
D	**Y**	**2.6.1.8**	The System must provide the ability to prioritize an outbreak/outbreak investigation. Priorities could be 'High - Immediate', 'Medium', 'Low', etc.
D	**Y**	**2.6.1.9**	The System must provide the ability to accommodate a link or references between cases, contact, and outbreaks, identifying the cases which are part of an outbreak.
D	**N**	**2.6.1.10**	The System must provide the ability to assign investigation status to outbreaks. Status could be: new, during investigation, confirmed, open, close
D	**Y**	**2.6.1.11**	The System must provide the ability to generate final reports related to an outbreak that are disease- or transmission-mode specific.
D	**Y**	**2.6.1.12**	The System must provide the ability to generate outbreak questionnaires (ad hoc forms) to be defined and entered. TB - System must also allow and manage additional disease/agent-specific data such as laboratory and clinical results to be entered. TBCB can provide TB-specific data elements.
D	**Y**	**2.6.1.13**	The System must provide the ability to capture information about activities performed to limit an outbreak, such as quarantines or isolations imposed as appropriate on the Outbreak form, contact form, and the case form. In addition to intervention activities, the System should also capture other activities or events, such as media reports, key meetings, changes in case definitions or other operational definitions, etc.
D	**Y**	**2.6.1.14**	The System must provide the ability to assign an investigator to an outbreak.

2.7 Associated Case Processing Functions

2.7.1 To Do Actions (Task List) Requirements			
Rank	**Demo**	**Req ID**	**Description**
D	**N**	**2.7.1.1**	The System must provide the ability to enter "To-Do items/actions" into the System. A To-Do action must contain information about the activity to perform (for example, call a contact, send a letter, call a client, visit a client), when this activity is due, status on the activity (new, in progress, waiting for confirmation, completed/closed), and owner of the action.
D	**N**	**2.7.1.2**	The System must provide the ability to assign a To-Do action to another individual, more than one individual, or group of individuals.
D	**N**	**2.7.1.3**	The System must provide the ability to allow the review of To-Do actions, for example by having access to To-Do lists by date or by status as well as a list of my own To-Do actions.
D	**N**	**2.7.1.4**	The System must provide the ability for follow-up activities (*e.g.,* follow-up forms and checklists for follow-up activities). These follow-up activities may be disease-specific and sometimes occasion-specific, such as an outbreak situation. The System will automatically link To-Do lists to specified conditions.
D	**N**	**2.7.1.5**	The System must provide the ability to generate reminders, letters, reports, etc based on scheduled activities in the System. **IZB Note**: Important function for perinatal hepatitis B case management (IZB).

2.7.2 Geocoding and Mapping Requirements			
Rank	**Demo**	**Req ID**	**Description**
D	**Y**	**2.7.2.1**	The System must provide address standardization functionality for all captured address and location information.
D	**Y**	**2.7.2.2**	The System must be able to utilize (interface with) an external geocoding service in a secure and confidential manner.
D	**Y**	**2.7.2.3**	The System will provide, at minimum, full standardized street address information and a record identifier (not name) to the geocoding service.
D	**N**	**2.7.2.4**	The System must provide the ability to accept, at minimum, latitude, longitude, accuracy code, and region information (census tract, zip code, local health jurisdiction) associated with the geocode from the geocoding service. Region information must be stored separately from that entered by users (i.e., cannot overwrite user-entered region data/fields).
D	**Y**	**2.7.2.5**	Alternatively to 2.7.2.2-4 above (use of external geocoding service), the System must itself provide comparable geocoding for all captured standardized address and location information.
D	**N**	**2.7.2.6**	If the System provides geocoding internally, vendor to keep geocoding files and links current. Describe how this is accomplished.
D	**N**	**2.7.2.7**	If the System provides geocoding internally, describe the modularity of geocoding and if it is possible to share this functionality with other systems.
D	**N**	**2.7.2.8**	The system must allow the ability to manually enter and edit geocoding information (e.g., as collected via GPS in the field), and to correct the assigned region or jurisdiction when necessary (e.g., location near a jurisdiction boundary creates conflicting location associations). Manually entered or corrected geocode information should not be overwritten indiscriminately by the geocoding engine (external or internal); i.e. the system should provide a mechanism to allow record-level end-user control (e.g. by a registry manager) of whether or not the manually entered/corrected geocode fields are overwritten by subsequent address changes (which trigger automated geocoding requests).
D	**N**	**2.7.2.9**	The system must provide the ability to manually initiate the “re-geocoding” of an address, overriding the existing geocode.

2.7.2 Geocoding and Mapping Requirements			
Rank	**Demo**	**Req ID**	**Description**
D	**N**	**2.7.2.10**	For addresses which were not geocoded on the initial pass, or where the geocode accuracy per 2.7.2.4 indicates geocode not to the level of street segment (such as to a zip-code or county centroid), the system should provide functionality to identify these addresses and to facilitate: • The edit of the address and manual reinitiating of the geocoding per 2.7.2.9, and/or • Allow for the use of an external or alternate geocoding service which may have very up-to-date reference files (i.e. use a service where the interface might be too slow or service too expensive for routine geocoding). • Provide a facility for batch re-geocoding of low accuracy or null geocodes which could be executed after updates to the regular service or internal reference tables have been applied. • Provide a report of addresses updated with geocode via batch processing or external services.

2.7.3 Search Requirements			
Rank	**Demo**	**Req ID**	**Description**
M	**Y**	**2.7.3.1**	The System must provide a Search function with parameters for finding data in the system. Searchable data elements will be based on business rules provided by DCDC, branches, and LHDs. **Note**: Search displays will depend on roles and privileges as defined for the user.
M	**Y**	**2.7.3.2**	The System must provide multiple methods for the users to find the case they want to work with in the System. Either via patient searches or via list of cases (*e.g.,*. all cases by disease, all cases with a certain status, all cases assigned to a jurisdiction, all cases assigned to me or my role, all cases with high priority, etc).
M	**Y**	**2.7.3.3**	The System must provide multiple methods to find a contact in the System and access contact information (*e.g.* phone numbers, address etc).

2.7.4 Master Index(s) Requirements			
Rank	**Demo**	**Req ID**	**Description**
M	**Y**	**2.7.4.1**	The System must provide a master index of all persons of interest to avoid duplication.
D	**Y**	**2.7.4.2**	The System must provide a master index of all organizations of interest to avoid duplication. (organizations and roles? – orgs are labs, hospitals, other entities).
M	**Y**	**2.7.4.3**	The System must provide a master index of all providers of interest to avoid duplication. System should contain a field for HIPAA National Provider Identifier and use any validity edits available from the National Provider database.
M	**Y**	**2.7.4.4**	The System must provide access to all indexes based on user permissions.
M	**Y**	**2.7.4.5**	The System must provide the ability to perform searches of all indexes on relevant data. System should provide a mechanism to search whether an entity exists, choose from a potential result set, or offer the option to create new entity if no match is found. “Relevant data” for searches will be provided by DCDC and Branches.

2.7.4 Master Index(s) Requirements			
Rank	**Demo**	**Req ID**	**Description**
M	**Y**	**2.7.4.6**	For users with the appropriate security permission, the System must provide the ability to adjust matching threshold for search criteria matching.
M	**Y**	**2.7.4.7**	The System must provide the ability to merge and logical deletion of records in the person, provider and organizational indexes. Merge/logical deletion allows a user to merge duplicate records and designate a primary record in the index. When a record is merged all history and linked information should be retained (e.g. cases, case reports, assignments etc). When purged from the active index, a duplicate record should not be physically deleted but marked inactive and retained for history.
D	**N**	**2.7.4.8**	The System must provide the ability to notify responsible users when records in the master indexes have been logically deleted (for example by logging the deletion, or by alerting the users).
M	**Y**	**2.7.4.9**	The System must provide the ability to automatically match/merge of person records if a defined high level of matching confidence is reached. Similarly, the System should disallow match/merge if a defined low matching confidence level is reached. System should be capable of displaying to the user match candidates to select when the matching confidence level is between the high and low levels. If System finds a conflict, the user will be notified and manual intervention will be permitted.
D	**Y**	**2.7.4.10**	The System must provide the ability to display merged records.
O	**N**	**2.7.4.11**	The System must provide the ability to interface with an external Master Person Index (MPI) to instantiate persons so that uniqueness can be established across multiple systems including Web-CMR. The vendor should describe how the system could interface with an external MPI to accomplish person search and instantiation of the functions described above.

2.8 Data Output

2.8.1 Reports and Queries Requirements			
Rank	**Demo**	**Req ID**	**Description**
M	**Y**	**2.8.1.1**	The System must provide the ability to create and print displayed report information in various output formats, including PDF, HTML, RTF, and TXT.

2.8.1 Reports and Queries Requirements			
Rank	**Demo**	**Req ID**	**Description**
M	**Y**	**2.8.1.2**	The System must provide the ability to report on transactional data with a desirable response time. Some examples include current case counts, clusters of cases, and high risk cases.
O	**Y**	**2.8.1.3**	The System must provide the ability to access data for direct query. For example, SQL query, or query pass-thru from SAS to DB via ODBC. Desirable that system provides data views (pre-defined SQL views) to allow access to user-entered data. It is desirable that the system allows for user created SQL Views useful for analysts within the analytic system (may require defining and submitting View specs to a DBA)
M	**Y**	**2.8.1.4**	The System must provide the ability to create and generate pre-defined reports that may or may not include user-defined parameters. (Automated reports are needed of at least the same level as in currently used systems (AVSS, STD morb, etc.). Three types of reports are required: • Transactional real-time (run against the transactional database) • Analytic (run against the warehouse database) • Summary (contains aggregated data fields) **Appendix C** contains a list of required reports for all DCDC Branches. The list shows which reports are run against the transactional database (real-time) and which reports are run against the analytic database (warehouse database). It also shows summary reports that require data aggregates. **Note**: Also see Requirement 1.3.1.13 for information about confidentiality notices on printed reports. Also see Requirements 2.7.1.4 and 2.7.1.5.
M	**N**	**2.8.1.5**	**Local Health Departments Quality Control Report**: The purpose of this report is to view whether submitted data meets Registry Quality Control requirements as specified in TB Registry Quality Control Listings.
M	**N**	**2.8.1.6**	**Provide Local Health Departments Access to Their own Quality Control Reports**: Capability for LHDs to run, view, and print their own QC reports. The LHD Local Administrator would perform this activity.
D	**N**	**2.8.1.7**	The System must provide the ability to use specified data fields to generate reports that display aggregate data results. (See requirement 2.7.1.3)
D	**Y**	**2.8.1.8**	The System must provide the ability to generate ad hoc reports.

2.8.1 Reports and Queries Requirements			
Rank	**Demo**	**Req ID**	**Description**
D	**Y**	**2.8.1.9**	The System must provide the ability to facilitate the creation of reusable, sharable templates for ad hoc reporting. A template is a pre-defined set of questions used to select data for a report.
D	**N**	**2.8.1.10**	The System must provide the ability to calculate and present disease rate statistics utilizing Department of Finance population data for denominators. As an integral part of this requirement, system to provide the ability to store and access tables of common reference denominators such as Department of Finance population data, FIPS, USPS Zip codes, etc. **IZB**: Following are links to the DOF population tables that IZ uses. The data dictionary for each table is documented in the first line of the table as well as on the site. IZ uses the yearly files in these links, rather than the county files. Years 1970 - 1989 http://www.dof.ca.gov/HTML/DEMOGRAP/Data/RaceEthnic/Population-70-89/RaceData_70-89.asp Years 1990 - 1999 http://www.dof.ca.gov/HTML/DEMOGRAP/Data/RaceEthnic/Population-90-99/RaceData_90-99.asp Years 2000 - 2050 http://www.dof.ca.gov/HTML/DEMOGRAP/Data/RaceEthnic/Population-00-50/RaceData_2000-2050.asp **TBCB**: uses the same DOF data files that IZB lists, above. For the 3 cities, TB also uses State of California, Department of Finance, E-4 Population Estimates for Cities, Counties and the State, 2001-2006, with 2000 Benchmark. Sacramento, California, May 2006. or State of California, Department of Finance, E-1 Population Estimates for Cities, Counties and the State with Annual Percent Change — January 1, 2005 and 2006. Sacramento, California, May 2006. **STDCB**: DOF data files used by **STDCB** are listed in “STD Automated Reports.” shown in **Appendix C.**

2.8.2 Export Requirements			
Rank	**Demo**	**Req ID**	**Description**
M	**Y**	**2.8.2.1**	The System must provide the ability to export a defined set of data elements for a variety of users, use cases and for consumption by various applications. This includes a flat delimited file structure to readily allow import into common database, spreadsheet, statistic, visualization, analytic and other tools. The default export file structure should be a comma-delimited format, and preferably the system should allow for the dynamic selection or free entry (with validation against a common value set such as a pipe, tilde, tab, etc.) of a delimiter character that best fits the user's needs. It is also recommended that these export files be encoded in UTF-8 (Unicode) to ensure broad interoperability with applications, internet-based protocols and the various operating system file structures. The output files must also include a header row that identifies the column name and the column name should clearly describe the type of content to the typical user. Acronyms or abbreviations in these headers should be avoided. There should also be an associated reference document provided in a package with the export or referenced elsewhere (i.e. as a link) that is current and accurate and describing the file structure, including column names, data types, field size, list of permissible values (if appropriate), associated question test if the data is derived from a form field and preferably the source table. Because these exports may pull data from multiple tables or databases, it would be ideal to identify this source as well. Exportable information includes all data collected on, but not limited to, CMRs, Case Report Forms, end-user defined forms and lab reports. Essentially any data entered in the system should be exportable.
M	**Y**	**2.8.2.2**	The System must provide a graphical user interface (GUI) and methodology to filter data residing in the application database for data export. The GUI would provide selection parameters to customize the export file. Examples of parameters would include, but not be limited to, jurisdiction, disease/condition, form, date ranges or any other range values of a variable, and selection of data elements to include. For example, in the TB RVCT report, All RVCT report variables, including created variables, and State User Defined Fields (UDFs) will be included in the export file (example: MDR-TB would export linked data from ELR and RVCT data sources).
M	**Y**	**2.8.2.3**	The System must provide the ability to export data to XML and XML should be the default method for text based file persistence and export for subsequent conversion to other formats for importing into various applications. These transforms to a specific application XML (e.g. spreadsheet XML) format would support the seamless rendering of the data into a set of applications commonly used by public health personnel and this functionality should be transparent to the user. Although the requirement regarding the minimum expectation of a flat comma delimited file with headers in 2.8.2.1 may involve the direct creation of this file from a database query by a particular solution, it is expected that XML would be the intermediate processing step with continued transformation to this delimited file as well as the other formats described (see below). In other words, the GUI would provide data export options to standard platform and application agnostic structures (e.g.

2.8.2 Export Requirements			
Rank	**Demo**	**Req ID**	**Description**
			delimited text) as well as export and download to a format readily consumable by a proprietary application. The user would not require intermediate data manipulation or preprocessing steps to import this data in this case, unless the user wished to export and download the source XML file for customized post-processing. Although not inclusive, the minimum expectation is seamless integration into the following proprietary applications: 1) Microsoft Excel 2) Microsoft Access 3) SPSS 4) SAS For data export and transformation, XML files must be well-formed and they must validate against a defined schema. XML Schema should be the default validation mechanism. It is expected that the system support the complete transformation lifecycle or serialization of source XML documents to final output document formats using XSLT file templates or scripts for conversion into common file types such as mentioned above, including screen display as text, XHTML and PDF. Integration of other customized schemas is desirable, however specific transform use cases and scripts will evolve over time and cannot be elucidated in this requirement. Schemas used for validation should be referenced from a single external namespace using a public identifier in the form of a Uniform Resource Identifier (URI) within the root element so that changes or updates required to modify the schema is universal and does not require changes to each XML file if the schema is embedded within each file. This full exposure also allows CDHS program and adjunct staff to readily access these schemas so they be used to write transforms according to future requirements (e.g. new PDF forms or HL7 clinical document formats).
M	**Y**	**2.8.2.4**	The System must provide the ability for users to define (filter) criteria for data export. The user should be able to save defined export template(s).
O	**N**	**2.8.2.5**	The System must provide the ability for users to set standard batch exports at a specified time and date.

2.8.3 Printing Requirements			
Rank	**Demo**	**Req ID**	**Description**
M	**Y**	**2.8.3.1**	The System must provide the ability to for a Provider to print the CMR they have entered. System should provide the following abilities for the provider to: • Print to printer (A "print-friendly" option will be available [see definition in the Glossary in this document]) • Save to file The artifact created from either procedure should contain the following two items: • Status of the document (e.g. "successfully submitted", "transaction completed", "pending", etc.) • A Unique Identification (UID) or confirmation code shall be bound to the submitted CMR report and can be used for tracking. This provides a non-repudiation method that can be retained by the party who submitted the CMR. • A confidentiality statement must also be displayed on the printed CMR (See Requirement 1.3.1.13.)
M	**Y**	**2.8.3.2**	The System must provide the ability to print displayed forms and reports. A "print-friendly" option must be available for printing forms and reports.
M	**Y**	**2.8.3.3**	The System must provide the ability to print to PDF and TXT formats at a minimum. Additionally, printing to ODF and RTF formats would be desirable.
M	**Y**	**2.8.3.4**	The System must provide the ability to print a subset or all attachments associated with a case. At minimum, there would be a *comment* or *annotation* field attached to the file by the user who uploads the attachment. The user would be directed to provide sufficient details to identify and describe the source document. Data type would be ASCII text with some character limit (e.g. 255). Filenames are insufficient. The system should provide text to assist the user in creating/using intuitive file names. The system would keep track of issue dates (e.g. timestamp when uploaded or added to the system). NOTE: Refer to 2.2.2.3. For attachment metadata requirements.

2.8.4 Alerts - Statewide Alerting Requirements (via Health Alert Network)

Note: Alerts refer to communications directed at human recipients. All Web-CMR messaging requirements (i.e. exchange of data from one computer system to another) are listed in the Integration Requirements section of this document. Messaging is used to forward/receive ELRs and CMRs between jurisdictions, and to exchange transferred cases.

Rank	Demo	Req ID	Description
M	**Y**	**2.8.4.1**	For users with the appropriate security permission, the System must provide the ability to configure and maintain criteria to identify unusual or dangerous occurrences of disease conditions based on case counts. The configurable criteria should include the disease condition, case classification, case count, time interval, and region/jurisdiction (e.g. 50 confirmed cases of hepatitis A in a 6-day interval in the Sacramento Region (4 adjacent counties)). Alerts may be designated for delivery to specified roles as maintained in the HAN public health directory (e.g. epidemiologists, TB controllers, county health officers). The system will monitor case activity and raise alerts or notifications on the basis of these configured alerting criteria. The system will allow configuration of periodicity of alerts.
M	**Y**	**2.8.4.2**	The System must provide the ability to construct and pass role-based alerts to an external Health Alert Network (HAN) for distribution to local and state users registered in the HAN's California public health directory, which maintains the contact information and roles for individuals. Alerts may be formatted according to PHIN Communication and Alerting Protocol (CAP) implementation guidance or according to negotiated interfaces with California HAN receivers. The alerts passed to the HAN may be directed to specific jurisdictions and/or roles.
M	**Y**	**2.8.4.3**	The System must provide the ability to recognize potential bioterrorism (BT) agents and other high-risk agents in in-coming lab report data (based on a user-defined list of agents), construct alerts to the affected jurisdiction(s) and programs based on the lab report data, and electronically transmit the BT alerts to an external HAN environment for distribution to designated roles (e.g. BT coordinators). **TB Note**: The presence of MDR-TB qualifies as a notification condition of TB – to both LHD and state. **IZB Note**: The presence of Smallpox qualifies as a notification condition.

2.8.5 Notifications - End-user Notifications Requirements (via Web-CMR prompts, lists, and functions)

Note: End-user notifications apply only to direct authorized users of Web-CMR, and are delivered on-line when the end-users are logged into a Web-CMR session and can check work queues, notification queues, etc. In addition to these notifications, data input editing error prompts are required but are covered in section titled "**Field Validations and Error Checking for Forms"**.

Rank	Demo	Req ID	Description
D	**Y**	**2.8.5.1**	The System must provide the ability to notify LHD and State end-users when new CMRs or ELRs are received for their jurisdiction or program, and when new cases are created for their jurisdiction or program, e.g. by placing them in a designated input queue or highlighting them within an assigned case list. The System should allow users with the appropriate permissions to determine (configure) which disease notifications are placed within the queue and which bypass the queue.
D	**Y**	**2.8.5.2**	The System must provide the ability for a provider/reporter with appropriate permissions to receive a request for more information from the local or state health department. Requests should be stored within the System, and the only information sent via e-mail should be an alert to read information in the System.
D	**N**	**2.8.5.3**	The System must provide the ability for a provider/reporter to receive feedback on a submitted report (*e.g*. this is not a notifiable condition or this case does not meet case definitions). Feedback should be stored within the System, and the only information sent via e-mail should be an alert to read information in the System.
O	**N**	**2.8.5.4**	The System must provide the ability for two-way data and information exchange between LHDs, and between LHDs and the state. For example, the system should allow an LHD to (1) receive a request for more information about a case and (2) respond to the request for more information (refers principally to "free-form text notes.")
D	**N**	**2.8.5.5**	The System must provide the ability to automatically notify specified role of required tasks based on specific rules (e.g., notify clerk to send out a letter when priority 2 syphilis reactor identified; notify physician to complete CMR if lab report received but not a CMR with 14 days).
D	**Y**	**2.8.5.6**	The System must provide the ability for the LHD to notify the State when a case is ready for State review (e.g. when the case reports are completed.)
D	**Y**	**2.8.5.7**	The System must provide the ability to assign a case confirmation status by both an LHD and the State (e.g. suspect, probable, confirmed). If the State case confirmation status differs from LHD case status, the LHD should be notified.
D	**Y**	**2.8.5.8**	The System must provide the ability to manually transfer cases between jurisdictions. When a case is transferred all history should be maintained. The receiving jurisdiction should receive a notification of the transferred case.
D	**Y**	**2.8.5.9**	The System must provide a confirmation of transfer notification and acceptance or rejection of the transfer.

2.8.5 Notifications - End-user Notifications Requirements (via Web-CMR prompts, lists, and functions)

Note: End-user notifications apply only to direct authorized users of Web-CMR, and are delivered on-line when the end-users are logged into a Web-CMR session and can check work queues, notification queues, etc. In addition to these notifications, data input editing error prompts are required but are covered in section titled "**Field Validations and Error Checking for Forms"**.

Rank	Demo	Req ID	Description
D	**Y**	**2.8.5.10**	The System must provide the ability to notify users when a follow-up laboratory report has been reported for an existing case or ELR

Glossary of Terms

The following terms are used in software requirements throughout this document:

Note: Glossary last updated 02/01/07.

Term	Definition	See Also
A/B Notification	A/B Notification (Report on Alien with Tuberculosis CDC 75.17) form is sent to the CDHS-DCDC TBCB from a Local Health Jurisdiction who has received an immigrant alien classified with Class A Non-communicable TB or Class B Not Infectious TB.	CDC CDHS DCDC TBCB
AIDS	Acquired Immune Deficiency Syndrome (AIDS). See HIV for definition details.	HIV HARS
Alert	**Alert, message**: An Alert may be a type of notification delivered pro-actively to an individual via personal communication mechanism such as a cell phone, pager, or e-mail address. In the case of Web-CMR, the need for alerts will be determined within the application based on alert triggering rules, but the application will communicate these alerts to a separate health alert network service for distribution to public health and emergency preparedness individuals across the state. **Alert, system**: An Alert may be a type of notification, typically an error message, generated by the computer operating system or application program to alert the user to an error condition, such as timing out of the application, or a “404” Page Not Available message.	Notification
Alien	An "Alien" is defined by the Immigration and Customs Enforcement Agency (ICE) as "any person not a citizen or national of the United States."	
Application, software	An *application*, or application program, is a software program that runs on a computer. Web browsers, e-mail programs, word processors, games, and utilities are all applications. The word "application" is used because each program has a specific application for the user, such as word processing, patient management, and spreadsheet preparation. In contrast, *system* software programs run in the background, enabling applications to run. These programs include assemblers, compilers, file management tools, and the operating system itself. Applications are said to run on top of the system software, since the system	System

Term	Definition	See Also
	software is made of "low-level" programs. While system software is automatically installed with the operating system, you can choose which applications you want to install and run on your computer. **Note**: The terms "application" and "application program" are synonymous; however, there could be a technical difference if both terms are used in the same conversation. In that case, "application" would refer to the complete set of files that have to be installed (executables, configuration files, ancillary data files, etc.), whereas the "application program" would refer to just one executable file.	
Archive	*Verb*: To compress one or more files and folders into a single file for backup or transport. Although archived files may remain on the same computer, the term implies data retention, and archived data are typically stored in a secondary location for backup and historical purposes. *Noun*: A file that contains one or more compressed files. Most archive formats are also capable of storing folders in order to reconstruct the file/folder relationship when decompressed.	Backup
Area	A virtual area in WebCMR, in which one or more Local Health Jurisdictions are assigned to the area (one or more areas may comprise a “region”).	Region
ARPE	The "Aggregate Reports for Tuberculosis Program Evaluation" (ARPE) is an annual summary of the core activities of eliciting and evaluating contact to TB cases and treating the contacts that have latent TB infection. There are two forms used in California to report contact investigation: The "California ARPE Follow-up and Treatment for Contacts to TB Cases" (CA ARPE-CI), and CDC ARPE "Targeted Testing and Treatment for Latent Tuberculosis Infection" (ARPE-TT) (only LHDs with CDC-funded targeted testing projects in California are required to complete the ARPE-TT form).	
Associate	For the purposes of STDs, “associate” is defined as a person identified by an original patient’s contact that is at risk for an STD (the contact of a contact).	
Back-end, software	Any software performing either the final stage in a process, or a task not apparent to the user. A common usage is a verification of permissions based on user-class and security. The end-user accesses the application and pages are retrieved based on user-class permissions.	Front-end
Backup	*Verb*: To make a copy of important data onto a different storage medium for safety. *Noun*: Additional resources or duplicate copies of data on different storage media for emergency purposes.	

Term	Definition	See Also
	Backup program: Software that copies data from a single machine or from selected computers in a network to a secondary storage medium. Backups can be scheduled at periodic intervals, or individual files can be automatically backed up right after they have been updated. **Backup types**: • **Full Backup**: Backs up all selected files. • **Differential Backup**: Backs up selected files that have been changed. This is used when only the latest version of a file is required. • **Incremental Backup**: Backs up selected files that have been changed; but if a file has been changed for the second or subsequent time since the last full backup, the file does not replace the already-backed-up file; rather it is appended to the backup medium. This is used when each revision of a file must be maintained. • **Delta Backup**: Similar to an incremental backup, but backs up only the actual data in the selected files that has changed, not the files themselves.	
CAHAN	California Health Alert Network (CAHAN) is a CDHS web-based system designed to broadcast warnings of impending or current disasters affecting the ability of health officials to provide disaster response services to the public. See http://www.dhs.ca.gov/epo/HANPrograms/EPOCAHAN.html	HAN
CalPHIN	California Public Health Information Network (CalPHIN) is an organization whose goal is to provide timely and secure access to quality public health data for surveillance, analysis, and decision making, respecting the confidential nature of private information. California launched the CalPHIN initiative to provide an integrated public health information system to effectively serve the data needs of the local, state, and federal public health workforce and California's citizens. CalPHIN serves to integrate relevant health and disease information along with laboratory results and surveillance data from the many members of the State's public health system. See http://www.calphin.dhs.ca.gov/.	PHIN
Case	*In patient management*: A disease episode that meets the case classification and case definition criteria and is formally assigned to a **patient** under the care of the provider and/or LHD. The case will be reported via a CMR, and may have one or more Case Reports associated with it. A patient may be assigned one or more cases (but only one case per disease episode). *In epidemiology*: A countable instance in the population or study group of a particular disease, health disorder, or condition under investigation. Sometimes, an individual with	Case Classification Case Definition Case Report

Term	Definition	See Also
	the particular disease.	
Case Classification	A method established by CDC for classifying cases, the classifications are as follows: **Clinically compatible case**: a clinical syndrome generally compatible with the disease, as described in the clinical description. **Confirmed case**: a case that is classified as confirmed for reporting purposes. **Epidemiologically linked case**: a case in which a) the patient has had contact with one or more persons who either have/had the disease or have been exposed to a point source of infection (i.e., a single source of infection, such as an event leading to a food borne-disease outbreak, to which all confirmed case-patients were exposed) and b) transmission of the agent by the usual modes of transmission is plausible. A case may be considered epidemiologically linked to a laboratory confirmed case if at least one case in the chain of transmission is laboratory confirmed. **Laboratory-confirmed case**: a case that is confirmed by one or more of the laboratory methods listed in the case definition under Laboratory Criteria for Diagnosis. Although other laboratory methods can be used in clinical diagnosis, only those listed are accepted as laboratory confirmation for national reporting purposes. **Probable case**: a case that is classified as probable for reporting purposes. **Supportive or presumptive laboratory results**: specified laboratory results that are consistent with the diagnosis, yet do not meet the criteria for laboratory confirmation. **Suspected case**: a case that is classified as suspected for reporting purposes. **Note**: These classifications are not generally used for Tuberculosis (see 2.4.2.15 for TB ATS classifications, and 2.4.2.8 for TB validation process (see CDC documentation for Case Verification Criteria in the *TIMS Surveillance Import Utility* in **Appendix A**).	Case Case Definition Case Report
Case Definition	The laboratory or clinical criteria for a specific disease as defined by CDC in "Case Definitions for Infectious Conditions Under Public Health Surveillance" http://www.cdc.gov/epo/dphsi/casedef/index.htm. For most conditions, a person must meet the case definition to be a countable case. **Additional links to CDC case definitions**: **1997 Document:** MMWR, Recommendations and Reports, May 02, 1997 / 46(RR10); 1-55. Case Definitions for Infectious Conditions Under Public Health Surveillance HTML version:	Case Case Classification Case Report

Term	Definition	See Also
	http://www.cdc.gov/mmwr/preview/mmwrhtml/00047449.htm PDF version: http://www.cdc.gov/mmwr/PDF/rr/rr4610.pdf and attached (rr4610.pdf) **1990 document:** MMWR, Recommendations and Reports, October 19, 1990 / 39(RR-13); 1-43. Case Definitions for Public Health Surveillance. HTML version: http://www.cdc.gov/mmwr/preview/mmwrhtml/00025629.htm PDF version: ftp://ftp.cdc.gov/pub/Publications/mmwr/rr/rr3913.pdf	
Case Report	**Case Report**: The term "case report" as used in the Web-CMR requirements is a standardized form for the management and mandated reporting of a specific disease by an LHD. The form is transmitted to the State, and then to CDC. For example, the Report of Verified Case of Tuberculosis (RVCT) report is used to report a confirmed, active case of Tuberculosis. See Appendix XX for a list of required case report forms. Typically Case Report forms have a set of reporting regulations provided by CDC or other originating entity. **Note, the Case Report as used in Web-CMR requirements is not to be confused with a CRF**: *A Case Report Form (CRF) is a questionnaire specifically used in clinical trial research.*	Form Report
CDC	The Centers for Disease Control and Prevention (CDC) is the lead federal agency for protecting the health and safety of people at home and abroad, providing credible information to enhance health decisions, and promoting health through strong partnerships. CDC serves as the national focus for developing and applying disease prevention and control, environmental health, and health promotion and education activities designed to improve the health of the people of the United States. CDC, located in Atlanta, Georgia, USA, is an agency of the Department of Health and Human Services. See http://www.cdc.gov/	
CDHS	California Department of Health Services (CDHS) is part of the California Health and Human Services Agency. The CDHS is one of the largest departments in state government, with over 5,000 employees working in its Sacramento headquarters and over 60 field offices throughout the State. As part of its mandate, the CDHS administers a broad	

Term	Definition	See Also
	range of public and clinical health programs that provide health care services to Californians. See http://www.dhs.ca.gov/	
Character Format	Keyboard letters, numbers, or special characters (such as a punctuation mark or $). Characters are part of the standard (or extended) ASCII character set and/or it's variants (http://en.wikipedia.org/wiki/ASCII).	
CHOW	Community Health Outreach Worker	
Client	**Client, person**: A person or other (group, animal) using or requiring the services of a health or social services agency. The client is the direct beneficiary of a project or service. **Client, computer**: A system or a program that requests the activity of one or more other systems or programs, called servers, to accomplish specific tasks. In a client/server environment, the workstation is usually the client.	Patient Person Case
Cluster	A "cluster" is a concentrated group of disease cases occurring within a specific location or time period. The number of cases may or may not exceed the expected number; frequently the expected number is not known. These cases may or may not be related, and therefore may or may not represent an outbreak of disease.	Outbreak
CMO	Chief Medical Officer	
CMR	Confidential Morbidity Report (CMR) form is used to report certain suspected, lab-confirmed, and/or clinically diagnosed cases of communicable disease to local public health authorities. In California, the reporting of specific communicable diseases is mandated by Title 17, California Code of Regulations (CCR), §2500, §2593, §2641-2643, and §2800-2812: Reportable Diseases and Conditions. See http://www.dhs.ca.gov/publications/forms/pdf/pm110.pdf	
Cohort	A well-defined group of people who have had a common experience or exposure, who are then followed up for the incidence of new diseases or events, as in a cohort or prospective study. A group of people born during a particular period or year is called a birth cohort.	Contact
Communicable Disease	A "communicable disease" is any disease that may be transmitted directly or indirectly from one individual to another.	Disease
Co morbidities	Co morbidities are conditions that exist at the same time as the primary condition in the same patient (e.g., hypertension is a co morbidity of many conditions such as diabetes, ischemic heart disease, and end-stage renal disease).	
Component, software	A principal computational element and data store that execute in a system.	

Term	Definition	See Also
	Technically, a dynamically bindable package of functionality that is managed as a unit and accessed through documented interfaces that can be discovered at runtime. Pragmatically, components tend to fall into two major groups: technical components, which perform a technology-specific task that is application-independent (e.g., a graphical user interface control), and business components, which encapsulate a piece of business functionality.	
Condition	Rules encapsulate, codify or formally describe conditions that are disease states (primarily caused by a communicable disease in this domain).	Communicable Disease
Contact	A "contact" is a person who has had potential effective exposure to a person who has a communicable disease. Both of the following criteria must be met to consider a person exposed to the disease as a contact: 1) The Local and/or State Health Department believes the person has had significant exposure to a communicable disease, and 2) that exposure warrants investigation and other necessary action.	Index Case Source Case
Contact Investigation (CI)	A "potential contact" is a person who has been exposed to a communicable disease. Contact Investigation (or Contact Tracing) includes those activities designed to identify, prioritize, locate, and examine potential contacts. Based on the evaluation, the staff will determine which individuals have had sufficient exposure to be considered contacts and thereby warrant testing, evaluation, and/or treatment. If the results of the assessment indicate that the contact has acquired the disease and should be treated, a treatment plan is defined and treatment begins.	Contact Investigator
CS	Congenital Syphilis	
CT	Chlamydia	
Data	Raw facts and figures that a computer processes into usable information. Data such as cash receipts mean little until processed into information such as an open receivable balance. Also: re-interpretable representation of information in a formalized manner suitable for communication, interpretation, or processing. Data can be processed by humans or by automatic means.	
Data Archive	A static, independent copy of a related set of files for intermediate or long-term storage, usually to satisfy financial-reporting, audit, regulatory and ad hoc retrieval requirements. The primary files can be left intact or deleted when the archive is created.	
Data Dictionary	A repository of information about data that supplies the meaning of the data, its relationship to other data, its origin, its usage and its format. The data dictionary assists management, database administrators, system analysts and application programmers in effectively	

Term	Definition	See Also
	planning, controlling and evaluating the collection, storage and use of data. A data dictionary manages data categories such as aliases, elements, records, structure, stores, models, flows, relationships, processes, functions, dynamics, size, resource consumption and other, user-defined data attributes.	
Data Element	The data element (DE) is a unit of data for which the definition, identification, representation and Permissible Values are specified by means of a set of attributes Note: Meta-model construct is: Class.	
Database	An electronic filing system organized by fields, records and files. A field is a single piece of information, a record is a set of fields and a file is a collection of records. For a detailed description of "Database," see http://en.wikipedia.org/wiki/Database.	
Database, Analytic	For the purposes of the Web-CMR application, the "analytic" database provides storage of all data records for retention, retrieval, analysis, and reporting.	
Database, Transactional	For the purposes of the Web-CMR application, the "transactional" database provides real-time direct entry data transactions, such as form submission, editing, and viewing. For more information on database transactions, see http://en.wikipedia.org/wiki/Database#Transactions_and_concurrency.	
DCDC	Division of Communicable Disease Control (DCDC) of the CDHS works in partnership with local, national and international health officials, health care providers, and the public to monitor health, identify and investigate existing and potential health problems, develop and implement prevention strategies, conduct research, provide education and training, and formulate and advise on public health policy. See http://www.dhs.ca.gov/ps/dcdc/dcdcindex.htm	
Demographic Information	The "person" characteristics--age, date-of-birth, sex, race, ethnicity, and occupation--of descriptive epidemiology used to characterize the populations at risk.	Person
Disease	A pathological condition of a part, organ, or system of an organism resulting from various causes, such as infection, genetic defect, or environmental stress, and characterized by an identifiable group of signs or symptoms.	Case Definition
DOB	Date of Birth	

Term	Definition	See Also
DOT	Directly Observed Therapy (DOT) or supervised therapy involves the direct visual observation by a health care provider (e.g., outreach worker or nurse) or other reliable person (e.g., homeless shelter worker) of a patient's ingestion of medication. Delivering medication to a patient without visual confirmation of ingestion does not constitute DOT. Confirmation that the medication has been swallowed may sometimes be necessary. Using such techniques as having the patient swallow a glass of water or talk following ingestion, inspecting the oral cavity with the tongue raised by the patient, or using a tongue blade to inspect between the cheek and the gums are helpful in determining if the medication has been swallowed.	
Deduplication	In storage technology, deduplication essentially refers to the elimination of redundant data. In the deduplication process, duplicate data is deleted, leaving only one copy of the data to be stored. However, indexing of all data is still retained should that data ever be required. Deduplication is able to reduce the required storage capacity since only the unique data is stored. Deduplication is also written as de-duplication, and is synonymous with data reduction or commonality factoring.	Duplicate
Duplicate	One that corresponds exactly to another, especially an original. Often thought of as duplicate report (like a CMR), but could also indicate a duplicate observation (like two separate dates of birth for a person, based not on a duplicate report, but from the same observation for the same subject coming from two distinct input data sources (reports or forms).	Deduplication
EDI	Electronic Data Interchange (EDI) is a standard format for exchanging business data. An EDI message contains a string of data elements, each representing a singular fact, such as price, product model number, and so forth, separated by delimiters (a character that identifies the beginning and end of a character string). The entire string is called a data segment. EDI is one form of e-commerce, which also includes e-mail and fax.	
EDN	Electronic Disease Network (EDN) is a web-based system for notification of state and/or local health department about immigrants, refugees or asylees seeking permanent residency arriving in the US with TB conditions requiring follow-up. EDN is administered by CDC Division of Global Migration and Quarantine.	
ELR	Electronic Laboratory-based Reporting (ELR) is the transmission of data of public health importance from clinical laboratories to public health agencies in electronic format. Ideally, data transmitted by ELR would be automated and would use standardized codes for tests and results allowing for more timely and complete reporting. For information about the Electronic Laboratory Reporting (ELR) project, please see *ELR-*	

Term	Definition	See Also
	Business-Requirements.doc.	
EMPI	Enterprise Master Person Index (EMPI): A critical prerequisite for sharing information on patients and health plan members within an integrated delivery system (IDS). EMPIs (also known as "enterprise master patient indexes") uniquely identify patients and members, and cross-reference their identification numbers to link information in disparate systems.	
EMR	Electronic Medical Record (EMR): A critical prerequisite for sharing information on patients and health plan members within an integrated delivery system.	
Entity	Any concrete or abstract thing that exists, did exist, or might exist, including associations among these things EXAMPLE A person, object, event, idea, process, etc. An entity exists whether data about it are available or not.	
Epi-linked	Epidemiologically linked case; a case in which the patient has or has had contact with one or more persons who have or have had the disease, and transmission of the agent by the usual modes of transmission is plausible.	
Episode	A noteworthy happening or series of happenings occurring in the course of continuous events, as an episode of illness, a separate but not unrelated incident.	
Epidemic	The occurrence of more cases of disease than expected in a given area or among a specific group of people over a particular period of time.	Outbreak
Event	Forces of change that are one-time occurrences; an occurrence, especially one of importance; an outcome, issue or result of anything; something that occurs in a certain place during a particular interval of time. NEEDS Web-CMR definition of use.	
Extranet	A collaborative, Internet-based network that facilitates inter-company relationships by linking an enterprise with its suppliers, customers or other external business partners. Extranets use Internet-derived applications and technology to provide secured extensions of internal business processes to external business partners.	Internet Intranet

Term	Definition	See Also
Form	A form is generally used for the input or collection of information. Forms often are used in databases as the user front-end for data entry. The word is also often used to describe a paper form for the collection of information. Sometimes a form is created which is in the format of a required report, here the raw information may be collected using other forms, and the information needed to complete a report is manually compiled and re-entered onto a form which, when complete is itself a standard formatted report (see "report form")	
	Form, eform: Electronic form—data entry screen or linked series of screens. eforms, unlike paper data collection instruments which have a static format, may be dynamic.	
	Form, ancillary form: Possible alternative to work form -- a form	
	Form, report form: A type of form which accepts input of data needed for a report, usually in a specified format. Useful when data have been collected with manual processes and the end results of a process are manually entered or transcribed onto the form. That is, the form accepts all the information needed to complete a given report and no more. Hybrid between a report and a form - a specialized form which can be used for direct capture of data to be included on a report.	Report
	Form, sub form: A subsection of another form	
	Form, supplemental form: A form used primarily to capture non-standard data items relevant to an investigation or series of investigations or for capturing information of local importance, usually for a limited period of time.	
	Form, work form: A task-specific data-collection instrument. The idea of a work form is that it is related to routine work flow associated with standard case public health activities. This is an attempt to segregate "standard" data collection from "non-standard" or "supplemental" data collection. Possible alternatives might be "ancillary form" or "auxiliary form," The data elements captured by a work form should be drawn from the standard (to be) CalPHIN vocabularies and generally would capture observations which would contribute to a standard case report. An example work form or ancillary form might be a contact management form where the aggregated sum of contacts is a data item on a case report form.	
Front-end, software	An intermediary computer that does the set-up and filtering for the back-end system. Front-end software provides an interface to other programs in the back-end.	Back-end
GC	Gonorrhea	
Genotyping	Genotyping uses laboratory processes to describe the DNA pattern, or “fingerprint”, of a	

Term	Definition	See Also
	particular disease strain. Genotyping is used to compare disease strains from different individuals to assess the possibility of transmission among them. If the strains are the same, recent transmission between these individuals is likely to have occurred.	
Geo-coding	Geo-coding is the process of assigning geographic coordinates (e.g. latitude-longitude) to street addresses, as well as other points and features. With geographic coordinates, the features can then be mapped and entered into Geographic Information Systems." – http://en.wikipedia.org/wiki/Geocoding. Also see Harvard Geo-coding Project at www.hsph.harvard.edu/thegeocodingproject/webpage/monograph/ and The National Center for Health Statistics - www.cdc.gov/nchs/about/otheract/gis/pastreports.htm	GIS
GIS	Geographical Information Systems (GIS) is a collection of computer hardware, software, and geographic data for capturing, managing, analyzing, and displaying all forms of geographically referenced information. The leading developer of GIS is ESRI. ESRI GIS provides a common analytical framework in which public health authorities can understand problems and formulate a response, improving incident management and health planning. See www.GIS.com or www.ESRI.com	Geo-coding
Graphical User Interface	The graphical user interface (GUI) is the part of an application that the user sees on the display and works with to operate the application, using controls such as menus and forms.	
HAN	Health Alert Network (HAN) is a national program, providing vital health information and the infrastructure to support the dissemination of that information at the State and Local levels, and beyond. The Health Alert Network will function as PHIN's Health Alert component. See http://www.phppo.cdc.gov/han/	
HARS	HIV AIDS Registry System	HIV AIDS Registry
HBIG	Hepatitis B Immunoglobulin	
HBsAg+	Hepatitis B surface antigen positive. HBsAg is the most commonly used test for diagnosing acute HBV infections or detecting carriers.	

Term	Definition	See Also
HIPAA	Health Insurance Portability and Accountability Act of 1996 (HIPAA). The Centers for Medicare & Medicaid Services (CMS) is responsible for implementing various unrelated provisions of HIPAA, therefore HIPAA may mean different things to different people. HIPAA Health Insurance Reform: Title I of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) protects health insurance coverage for workers and their families when they change or lose their jobs. HIPAA Administrative Simplification: The Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA, Title II) require the Department of Health and Human Services to establish national standards for electronic health care transactions and national identifiers for providers, health plans, and employers. The regulations provide protection for the privacy of certain individually identifiable health data, referred to as protected health information (PHI). See http://www.hhs.gov/ocr/hipaa/	
HIV	Human Immunodeficiency Virus (HIV) disease is the pathogen that causes AIDS and encompasses all the condition's stages, from infection to the deterioration of the immune system and the onset of opportunistic diseases. However, AIDS is still the name that most people use to refer to the immune deficiency caused by HIV. An AIDS diagnosis (indicating that the person has reached the late stages of the disease) is given to people with HIV who have counts below 200 CD4+ cells/mm3 (also known as T cells or T4 cells, which are the main target of HIV) or when they become diagnosed with at least one of a set of opportunistic diseases. All 50 states and the District of Columbia report AIDS cases to CDC using a uniform surveillance case definition and case report form.	AIDS HARS
HL7	Health Level Seven (HL7): A set of application-level standards for community health information network initiatives, widely used in hospitals. Health Level Seven is one of several American National Standards Institute (ANSI)-accredited Standards Developing Organizations (SDOs) operating in the healthcare arena. Health Level Seven produces standards and specifications for clinical and administrative data. The HL7 Reference Information Model (RIM) provides a conceptual model of health care concepts: classes, attributes, data types, vocabulary codes. The HL7 Messaging Specification defines messages (i.e. data element sequences), trigger events, and sender/receiver roles, for common data exchanges. http://www.hl7.org/	LOINC SNOMED

Term	Definition	See Also
HTML	Hyper Text Mark-up Language (HTML). A structured document that is a collection of text, images and hyperlinks arranged and displayed to the user through a Web browser. Berners-Lee designed the first set of HTML tags using a tag style defined by the Open Source Initiative (OSI) for their Standard Generalized Markup Language (SGML). The HTML standard is currently defined and controlled by the World Wide Web Consortium (W3C) http://www.w3.org/ .	
HTTP / HTTPS	Hyper Text Transfer Protocol (HTTP / HTTPS): The set of standards that defines how data are requested and transferred between server and client computers. (HTTPS indicates a secure protocol.)	
Hyperlink	Most commonly found on web pages, a “hyperlink” is a link in the form of an icon, graphic or words that, when clicked, will transport the user to another file.	
IDB	Infectious Disease Branch of the CDHS	CDHS
Immunization	The creation of immunity usually against a particular disease; *especially*: treatment (as by vaccination) of an organism for the purpose of making it immune to a particular pathogen.	
Index Case	The “index case” is the first individual identified with active disease in the course of a disease contact or source case investigation.	Contact Source Case
Internet	The Internet is a network of more than 65 million computers in more than 100 countries covering commercial, academic and government endeavors. Originally developed for the U.S. military, the Internet became widely used for academic and commercial research. Users had access to unpublished data and journals on a huge variety of subjects. Today, the Internet has become commercialized into a worldwide information highway, providing information on every subject known to humankind.	Extranet Intranet
Intranet	A variation of the word Internet, an intranet is a restricted-access network that works like the Web, but isn't on it. Usually owned and managed by a corporation, an intranet enables a company to share its resources with its employees without confidential information being made available to everyone with network access. Intranets are mostly closed to outside access, but operate with the same features and elements as public-network, Internet sites.	Extranet Internet
Interoperability	According to the Interoperability Clearing House "interoperability is the ability of information systems to operate in conjunction with each other encompassing communication protocols, hardware software, application, and data compatibility layers. With interoperable electronic health records (EHRs), always-current medical information could be available wherever and whenever the patient and attending health professional needed it. At the same time,	PHIN

Term	Definition	See Also
	EHRs would also provide access to treatment information to help clinicians as they care for patients." See www.ichnet.org and http://www.cdc.gov/phin	
Investigation	A disease investigation conducted by an assigned staff member of a public health department.	
IT	**Information Technology (IT), governance**: The mechanism for assigning decision rights—and for creating an accountability framework that drives desirable behaviors—related to IT. **Information Technology (IT), infrastructure**: The underlying technological components that constitute an organization's system architecture. The seven components of IT infrastructure are hardware, operating system, network, database, development environment, user interface and application.	
IZB	Immunization Branch of the CDHS	CDHS
LHD **Local Health Department**	Local Health Department (LHD). The "local" as opposed to "state" level health department. The term is sometimes used interchangeably with "Local Health Jurisdiction," however "Jurisdiction" commonly refers to the geographical boundaries of the health service, while "Department" refers to the service and staff within the Department. See http://www.dhs.ca.gov/home/hsites/hdlinks.htm for links to California Local Health Departments.	LHJ
LHJ **Local Health Jurisdiction**	Local Health Jurisdiction (LHJ). See the entry for LHD (Local Health Department) for definition details.	LHD
LST **Local Stakeholder Team**	A WebCMR project team composed of stakeholders at Local Health Departments in California.	PMT
LOINC	Logical Observations, Identifiers, Names, Codes (LOINC) is a six-part coding scheme for describing laboratory tests (e.g. on specimens) and clinical tests (directly on living subjects). See Regenstrief Institute http://www.loinc.org/ or www.nlm.nih.gov/research/umls/loinc_main.html	SNOMED HL7
Message	A message carries or delivers a notification to the user or target; or the signal to the system. In the Web-CMR system, the “message” must meet the PHIN messaging standards and specifications.	Alert Notification
Module	An implementation unit of software that provides a coherent unit of functionality.	Software

Term	Definition	See Also
Morbidity	Any departure, subjective or objective, from a state of physiological or psychological well-being.	
MWWR	Morbidity and Mortality Weekly Report (MWWR). See http://www.cdc.gov/mmwr/	
NEDSS	National Electronic Disease Surveillance System (NEDSS). CDC is implementing NEDSS to better manage and enhance the large number of current surveillance systems and allow the public health community to respond more quickly to public health threats (e.g., outbreaks of emerging infectious diseases, bioterrorism, etc.). When completed, NEDSS will electronically integrate and link together a wide variety of surveillance activities and will facilitate more accurate and timely reporting of disease information to CDC and state and local health departments. Consistent with recommendations proffered in the 1995 report, Integrating Public Health Information and Surveillance Systems, NEDSS will include data standards, an internet based communications infrastructure built on industry standards, and policy-level agreements on data access, sharing, burden reduction, and protection of confidentiality. See http://www.cdc.gov/nedss/.	
NETSS	The National Electronic Telecommunications System for Surveillance (NETSS) is a computerized public health surveillance information system that provides the CDC with weekly data regarding cases of nationally notifiable diseases. Core surveillance data – date, county, age, sex, and race/ethnicity – and some disease-specific epidemiologic information for nationally notifiable diseases and for some non-notifiable diseases are transmitted electronically by the states and territories to CDC through NETSS each week. Data is transmitted in ASCII (American Standard Code for Information Interchange) format, which allows the NETSS system to integrate data from surveillance systems throughout the United States. See http://www.cdc.gov/EPO/dphsi/netss.htm.	
Notification	**In general**: A formal act of informing; an act or instance of notifying, making known or giving notice; a written or printed notice, announcement, or warning, often generated automatically. **In software**: Notifications are normally created automatically by an application immediately following an event or events that satisfy the rule that instantiates a trigger which subsequently evokes one or more notifications. Notifications may be further sub-typed or described as follows: • **Alert**: An unsolicited notice to warn about a past or pending event (e.g. “a confirmed case of smallpox was identified...”), a conflict, etc. Generally, an alert is considered to be a patent or overt or “push” type of notification such as an email.	Alert Message Event Trigger

Term	Definition	See Also
	An alert would be intended to evoke a subsequent action or business process and should provide feedback to the system that the cause of the alert has been resolved or mitigated. Alerts could also be classified based on a severity or acuity scale. Higher severity (greater sense of urgency) trigger events would be instantiated as alerts for example. • **Informational**: Provides feedback, such as within a non-repudiation scheme, or an acknowledgement. Example would include the inclusion of a transaction or confirmation number on a printed or saved CMR document or an emailed receipt of such a transaction. • **Prompt**: Primarily intended to elicit a response from the user (e.g. “Please supply a password”) • **Assistance**: e.g. “Although free text entry of the type of laboratory test is allowable, we recommend you choose from a pre-defined list test codes. Click here for more information”. • **Exception**: e.g. “You have already created a CMR report using that identifier” (may also be referred to as an “error message”). • **Workflow**: e.g. “You have completed Step 3 of 9” **In Web-CMR**: A notice displayed to a user when they log into the Web-CMR application system, e.g. via an attention screen or notification list that serves as a priority work queue. Notifications may be sent to individuals or to roles such as epidemiologists in a particular jurisdiction. E.g., the user (or users in a role) may be notified of priority situations, transferred cases, requested tasks, action items, etc. Notifications may be initiated by any registered application user.	
OIS	Office of Informatics and Surveillance of the CDHS	CDHS
Online	Online as opposed to "offline". When one is working on the World Wide Web, they are "online." For example, when a user accesses the internet and enters an RVCT form, they are entering the form "online."	
Outbreak	The occurrence of newly identified cases of disease above the expected or baseline level, over a given time period, in a geographic area of facility, or in a specific population group. The number of cases comprising an outbreak will vary according to the size of the population exposed, the timeframe, and the place of occurrence.	Epidemic

Term	Definition	See Also
	"Outbreak" is synonymous with "epidemic." Sometimes it is the preferred word, as it may escape the sensationalism associated with the word epidemic.	
PAM	Program Area Module (PAM): Program Area Modules are created and integrated with the CDC NEDSS Based System to incorporate disease specific data and processes.	NEDSS
Patient	A patient is a person who is formally admitted to the inpatient or outpatient service of a hospital, medical facility, or health department for observation, care, diagnosis, or treatment. The patient may be waiting for care, may be receiving it, or may have already received it. *In Web-CMR software requirements*: A "patient" must be assigned a case or cases (as opposed to a "person" or "client" who may exist in the master index but may not be assigned a case). A "patient" has a specific set of identifiers, such as name, birth date, etc. which are governed by the HIPAA confidentiality regulations	Case Person Client HIPAA
Pandemic	An epidemic occurring over a very wide area (several countries or continents) and usually affecting a large proportion of the population.	Epidemic Outbreak
Person	A person is a unique individual in the Web-CMR application. A "person" may or may not be assigned a case and may exist in the Master Index as a contact or other entity.	Case
PHIN	Public Health Information Network (PHIN) is CDC's vision for advancing fully capable and interoperable information systems in the many organizations that participate in public health. PHIN is a national initiative to implement a multi-organizational business and technical architecture for public health information systems. See http://www.cdc.gov/phin/	CalPHIN NEDSS
PMT	**Program Management Team**: The Web-CMR program management team for the State of California.	
Portal	A public portal is a high-traffic Web site with a wide range of content, services and vendor links. An enterprise portal is a Web-based presentation and interaction interface for users of enterprise applications and resources, such as a Web-CMR Provider. Enterprise portals provide windows into enterprise information, applications and processes.	
Print Friendly	Refers to an optional document format that prints correctly on standard 8.5" x 11" paper. When a Web page is printed, text and images may be truncated or not print at all and poorly located page breaks may waste paper. A printer friendly format ensures that all relevant information is printed in the appropriate margins with proper page breaks and that extraneous information like banners, advertisements, Flash displays, and animated	

Term	Definition	See Also
	graphics are suppressed or modified for printing.	
Process	**Process Model**: A framework describing the activities, functions, and processes of an organization. Processes in a process model are often defined in terms of their inputs and outputs. Process models often accompany data models; a data model does not reflect any action or flow of information and presents only a static view of data. **Process, preprocess**: Application of rules to form information at time of entry—typically before form data are committed to the main database—as might happen when rules are run against data entered to a web portal or browser-based rules—typically such processing would be restricted to data contained on a single form. **Process, post process (post-commit)**: Application of rules after form data has been committed to the database. The process would be triggered immediately after the record commit, or would be triggered by a workflow task, or would be executed in batch mode at specified intervals. A process run against data after being committed to the database might contain logic which includes data collected earlier with different forms or messages. These might include comprehensive data validation rules or evaluating case information against a case definition.	
Post-exposure prophylaxis	Measures taken after a person is exposed to an infectious disease, designed to prevent infection and further spread of disease.	
Provider	A person, agency, department, unit, subcontractor, or other entity that delivers a health-related service, whether for payment or as an employee of a governmental or other entity. Examples include hospitals, clinics, free clinics, community health centers, private practitioners, and the local health department. Health care providers who may provide certification of a serious health condition include: • doctors of medicine or osteopathy authorized to practice medicine or surgery (as appropriate) by the state in which the doctor practices • podiatrists, dentists, clinical psychologists, optometrists and chiropractors (limited to treatment consisting of manual manipulation of the spine to correct a sublimation as demonstrated by x-ray to exist) authorized to practice in the state and performing within the scope of their practice under state law • nurse practitioners, nurse-midwives and clinical workers authorized to practice under state law and performing within the scope of their practice as defined under state law • Christian Science Practitioners listed with the First Church of Christ Scientist in	

Term	Definition	See Also
	Boston, Mass. • any health care provider recognized by an employer or employer's group health plan's benefits manager • a health care provider listed above who practices in a country other than the United States and who is authorized to practice under the laws of that country.	
Quarantine	A restraint upon the activities or communication of persons or the transport of goods that is designed to prevent the spread of disease or pests.	
Query	A request for information placed to a computer system or database. Queries may be performed by human beings (for example, a Web user entering a query into a search engine or a database query using an SQL schema), but are also commonly performed by computers themselves (for example, a program placing an automated query to a database).	SQL
RDBMS	**Relational Database Management System (RDBMS)**: A database management system (DBMS) that incorporates the relational data model, normally including a Structured Query Language (SQL) application programming interface. It is a DBMS in which the database is organized and accessed according to the relationships between data items. In a relational database, relationships between data items are expressed by means of tables. Interdependencies among these tables are expressed by data values rather than by pointers. This allows a high degree of data independence.	SQL
Reactor	An individual with a reactive serologic test for syphilis.	
Race and Ethnicity	**Race**: As of 1997, The Federal Government's standards for classification of individuals by race have five racial groups: American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or other Pacific Islander, and White. These five categories are the minimum set for data on race for Federal statistics. The standards also offer an opportunity for respondents to select more than one of the five groups, leading to many possible multiple race categories. As with the single race groups, data for the multiple race groups are to be reported when estimates meet agency requirements for reliability and confidentiality. The 1997 standards allow for observer or	

Term	Definition	See Also
	proxy identification of race but clearly state a preference for self-classification. **Ethnicity**: The Federal government considers race and Hispanic origin to be two separate and distinct concepts. Hispanic or Latino origin includes persons of Mexican, Puerto Rican, Cuban, Central and South American, and other or unknown Latin American or Spanish origins. Thus Hispanics may be of any race.	
Record	A database record is a description of a single item as stored in a database. In the context of a relational database, a row—also called a record or tuple—represents a single, implicitly structured data item in a table. In simple terms, a database table can be thought of as consisting of rows and columns or fields. Each row in a table represents a set of related data, and every row in the table has the same structure.	
Region, regional	A virtual region in WebCMR, in which one or more areas (comprised of Local Health Jurisdictions) are assigned to the region.	Area
Registry	**Registry, data collection / reporting agency:** In California disease surveillance and reporting, the State registry for TB, STD, Immunization, and so forth is the organization that collects the data from LHDs for analysis and reporting. **Registry, database, master index**: An organized list of entities within the application that is accessible by a search function. Also referred to as an "Index." The registry may contain the names of persons, patients, animals, and locations.	
Report	A report is generally a presentation of information. In generic database applications reports are derived from data contained in the database. The data could have been imported, inserted from other databases or entered manually using a form. Reports generally deliver information, not accept information. A report from one application could serve as input to another application.	
	Report, officially reported: A case report completed by LHD and reported to the state. The LHD investigation could still be ongoing, however.	
	Report, Final: **(as in ARPE or Outbreak Final Report)**	
	Report, Preliminary: An event still under investigation by the LHD, but visible to the State as a preliminary report -- such reports would not contribute to CDC reporting nor would they contribute to case tabulations for public consumption.	
	Report, Provisional: An event officially reported to the state by LHD, but subject to review by the state, provisional reports will be sent to CDC and included in public tabulations, but such tables will be noted like "provisional and subject to revision"	

Term	Definition	See Also
	Report, Case Report Form (1): A report form associated with a specific disease and incident or investigation (may be used to indicate an outbreak report form, but should be used for individual cases). See "report form" and "outbreak report form" There should be a 1:1 correspondence between items on the form and items for the required report.	
	Report, Case Report Form (2): An official state form used for the reporting of a specific disease event.	
	Report, Database Report, Ad Hoc Report: Presentation of data which is contained in a database -- this could be a simple query or something requiring complex statistical analysis where the analysis is run using data directly from the database (without export/import).	
	Report, Electronic Lab Report: The data content from a lab report message sent from a laboratory to public health, as a special case of lab message, which could be a message generated by public health entry of a paper lab report.	
	Report, Lab Report: An incoming notice from a laboratory, whether paper, or electronic.	
	Report, Outbreak Report Form: A report form associated with a specific category of outbreak (e.g. Food borne, Waterborne, other/undetermined.	
	Report, Provider Report: Data content, usually a Confidential Morbidity Report (CMR), from a health care provider about a reportable morbidity event to Public Health (usually a Local Health Department).	
	Report, Report Form: A type of form which accepts input of data needed for a report, usually in a specified format. Useful when data have been collected with manual processes and the end results of a process are manually entered or transcribed onto the form. That is, the form accepts all the information needed to complete a given report and no more. Hybrid between a report and a form - a specialized form which can be used for direct capture of data to be included on a report.	
Requirement	A requirement describes a condition or capability to which a system must conform; either derived directly from user needs, or stated in a contract, standard, specification, or other formally imposed document. A requirement is a desired feature, property, or function to be met by the application. **Requirement, software**: A software requirement is a specification of an externally observable behavior of the system; for example, inputs to the system, outputs from the system, functions of the system, attributes of the system, or attributes of the system environment.	

Term	Definition	See Also
	Requirement, functional: A description of what a system should be able to do–a function it should perform.	
Role	A role is a definition of the behavior and responsibilities of an individual, or a set of individuals working together as a team, within the context of a software engineering organization. **Role-based**: The identification, authentication and authorization of individuals based on their job titles within an organization.	
RVCT	The Report of Verified Case of Tuberculosis (RVCT) form is used by CDC to collect specific TB surveillance data. All California health care providers are mandated to report to LHDs, within one day of diagnosis, all patients with suspected or confirmed TB (California Health and Safety Code sections 121361 and 121362). Providers use CMRs or locally developed TB CMRs to report suspected cases of TB to LHDs. The LHDs then submit RVCTs with specific information on the reportable cases of TB to the TBCB. The TBCB forwards the data on the reportable cases to CDC.	
SAS	Statistical Analysis Software	
SDN	Secure Data Network Standards and Procedure (SDN): Agency standards and operating procedures for the use of CDC/ATSDR Internet resources in the secure transmission and processing of sensitive or critical data and the support of sensitive or critical systems. See http://www.cdc.gov/od/hissb/docs/sdn3.pdf.	
Sentinel Event	Sentinel events are those cases of unnecessary disease, disability, or untimely death that could be avoided if appropriate and timely medical care or preventive services were provided. These include vaccine-preventable illness, late stage cancer diagnosis, and unexpected syndromes or infections. Sentinel events may alert the community to health system problems such as inadequate vaccine coverage, lack of primary care and/or screening, a bioterrorist event, or the introduction of globally transmitted infections.	
Signal	A Signal is an action that is used to convey information or instructions, typically by prearrangement between the parties concerned; an event or statement that provides the impulse or occasion for something specified to happen; an electrical impulse transmitted or received. Signals are carried within messages (e.g. the positive result for anthrax is the data signal carried within an HL7 message).	Message Alert Notification

Term	Definition	See Also
SNOMED	Systematized Nomenclature of Human and Veterinary Medicine (SNOMED) is a standardized vocabulary system for medical databases. Current modules contain more that 144,000 terms and are available in at least 12 languages. SNOMED has potential to become the standard vocabulary for speech recognition systems and computer-based patient records. For more information visit: www.snomed.org or www.nlm.nih.gov/research/umls/Snomed/snomed_announcement.html Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT) A version of the Systemized Nomenclature of Medicine (SNOMED) controlled medical vocabulary (CMV) released in January 2002 by the College of American Pathologists SNOMED division. It combines the content and structure of the SNOMED Reference Terminology (SNOMED RT) CMV with version 3 of the Clinical Terms CMV from U.K. National Health Service. See SNOMED and SNOMED RT. College of American Pathologists http://www.snomed.org/	LOINC HL7
Software	Software is basically a collection of computer instructions and data. Anything that can be stored electronically is *software*. The storage devices and display devices are *hardware*. The terms software and hardware are used as both nouns and adjectives. For example, it can be said: "The problem lies in the software," or "It's a software problem," meaning that there is a problem with the program or data, not with the computer itself. Software is often divided into two categories: **Systems software**: Includes the operating system and all the utilities that enable the computer to function. **Applications software**: Includes programs that do real work for users. For example, word processors, spreadsheets, and database management systems fall under the category of applications software.	Component Module System
Source Case	The patient is under investigation as the source case in a possible outbreak or as the source for one or more "contact" cases.	Case Contact

Term	Definition	See Also
SQL	Structured Query Language (SQL): A relational data language that provides a consistent, English-keyword-oriented set of facilities for data querying, definition, manipulation and control. It is a programmed interface to relational database management systems (RDBMSs). IBM introduced SQL as the main external interface to its experimental RDBMS, System R, which it developed in the 1970s. SQL statements include: • Data manipulation language (DML) statements: "select," "insert," "update" and "delete" • Data definition language (DDL) statements, including the "create" and "drop" statements for tables and indexes • Data control language (DCL) statements that control access and update privileges: "grant" and "revoke." SQL statements are called "dynamic" when they are not completely specified until the program is executed, and "static" when they are completely specified when the program is compiled. SQL is precise, because it is based on predicate logic, but is difficult for average users to deal with, and its most fruitful position is as a protocol for software-to-software connectivity, rather than for human-to-software access.	
STD	Sexually Transmitted Disease	
STDCB	Sexually Transmitted Diseases Control Branch of the CDHS	CDHS
STS	Serologic tests for syphilis.	
Surveillance, public health	Surveillance, public health: Surveillance is a term used to describe a set of public health activities that involve the reporting, tracking, analyzing and treating of communicable diseases. This systematic collection, analysis, interpretation, and dissemination of health data on an ongoing basis, provide knowledge of the pattern of disease occurrence and potential in a community, and helps to control and prevent disease.	
Suspect	A person for whom there is a high index of suspicion for a specific communicable disease (e.g., a known contact to an active case of the disease or a person with signs/symptoms consistent with the disease) who is currently under evaluation for the disease.	
SY	Syphilis	
Syphilis reactor grid	An administrative tool for triaging syphilis follow-up investigations based on a reactor's serologic titer, sex, age, and pregnancy status.	

Term	Definition	See Also
System	**System**: A means for describing the elements and interactions of a complete system including its hardware elements and its software elements (both application and system software). **System software**: System software refers to the files and programs that make up a computer's operating system. System files include libraries of functions, system services, drivers for printers and other hardware, system preferences, and other configuration files. The programs that are part of the system software include assemblers, compilers, file management tools, system utilities, and debuggers. System software is not meant to be run by the end user. Since system software runs at the most basic level of the computer, it is called "low-level" software. It generates the user interface and allows the operating system to interact with the hardware.	Application Component Module
Table, data	A set of data arranged in rows and columns.	
TIMS	Tuberculosis Information Management System (TIMS) is a surveillance and case management software application developed by CDC used by TB control programs in all 50 states, the District of Columbia, and various U.S. territories. (To be replaced by the CDC NEDSS.)	NEDSS
Trigger	A Trigger is anything as an act or event that serves as a stimulus and initiates or precipitates a reaction or series of reactions; to initiate or precipitate (a chain of events, scientific reaction, process, etc.) **In software**: A trigger is an act that is a result of rules applied to public health data. Single events alone, such as a positive case of smallpox, may not be sufficient to initiate an action. Analysis of multiple events and attributes within a decision support system, using static pre-defined rules or even a learning algorithm or Bayesian classifier may be the *a priori* actions before a trigger event can be created.	Notification Event
TB	Tuberculosis	
TBCB	Tuberculosis Control Branch of the CDHS	CDHS
UMLS	Unified Medical Language System (UMLS): Developed by the National Library of Medicine as a standard health vocabulary that enables cross referencing to other terminology and classification systems. Includes a metathesaurus, a semantic network, and an information sources map. Purpose is to help health professionals and researchers retrieve and integrate electronic biomedical information from a variety of sources, irrespective of the variations in the way similar concepts are expressed in different sources and classification systems. Has incorporated most source vocabularies. See	

Term	Definition	See Also
	http://www.nlm.nih.gov/research/umls/.	
User	A person who uses the Web-CMR system. That the “user” has the appropriate Web-CMR role(s) and permission(s) to perform the described activities within the system is implicit in the use of the term “user”.	Role
Web-based	A set of interconnected web pages, usually including a homepage, generally located on the same server, and prepared and maintained as a collection of information by a person, group, or organization. Web-based applications are usually accessed with a web browser (e.g., Microsoft Internet Explorer, Netscape).	
Vaccination	The introduction into humans or domestic animals of microorganisms that have previously been treated to make them harmless for the purpose of inducing the development of immunity.	
Vaccine	A preparation of killed microorganisms, living attenuated organisms, or living fully virulent organisms that are administered to produce or artificially increase immunity to a particular disease. Vaccines are administered through needle injections, by mouth and by aerosol.	
Validate, data	A procedure or protocol for verifying the values (data contents) of a form field. For example, in a simple validation, a "name" field may not allow number characters. If a user inadvertently entered a number in the "name" field, the validation program would display an error message informing the user that only alphabetical characters are acceptable in the field. Complex validations may execute programs to calculate and cross validate the results from several fields. For example, the patient’s birth date could not occur after the date they were diagnosed with a disease.	
Vector	An animate intermediary in the indirect transmission of an agent that carries the agent from a reservoir to a susceptible host.	
VPD	Vaccine-Preventable Disease.	
Zoonoses	An infectious disease that is transmissible under normal conditions from animals to humans.	Disease